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Interdisciplinary Behavioral Research

PRINCIPAL INVESTIGATOR: Dana H. Bovbjerg, Ph.D.

CONTRACTING ORGANIZATION: Mount Sinai School of Medicine
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The central goal of the Breast Cancer Behavioral Center is to further our understanding of the impact of biobehavioral factors on genetic aspects of breast cancer in African American women. The Center has three aims: 1) To support an integrated, interdisciplinary, Program of Research consisting of three synergistic Research Projects (with 4 supporting Cores), each of which addresses an important cancer topic and includes psychological and/or behavioral issues. Thus, we have research projects with implications for breast cancer etiology, behavioral issues, and their interaction; 2) To encourage the development of interdisciplinary thinking among the faculty involved in the Program of Research that can serve as a model for other institutions. Thus, we are demonstrating, by example, the utility of an interdisciplinary approach by working together on an integrated project that addresses important issues of interest to all members of the research team. We propose to bridge the gap between biobehavioral research and epidemiologic approaches. 3) To facilitate the development of truly interdisciplinary perspectives among new investigators in breast cancer research. Thus, we provide interdisciplinary training through both didactic and Ahands-on@ research, as well as informal seminars to outstanding young investigators who represent the future of the field.

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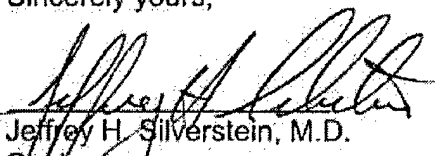
GCO Project # 00-0730 0001 03 CA *
Principal Investigator
Dana Bovbjerg, Ph.D.

ARMY

Dear Sir/Madam,

The project entitled **GENETIC FACTORS IN BREAST CANCER: CENTER FOR INTERDISCIPLINARY BIOBEHAVIORAL RESEARCH (PROJECTS 1, 2 AND 3)** includes activities involving human subjects. The Institutional Review Board of the Mount Sinai School of Medicine reviewed this project by expedited review in accordance with our assurance to the Department of Health and Human Services **FWA # 00005656**. This project met the criteria for Expedited Category **8b**. This project is approved for continuation for the period **10/4/2004** through **9/14/2005**. This project is approved to conduct at Queens Hospital Center pending receipt of approval of The Research Committee of that site.

Sincerely yours,


Jeffrey H. Silverstein, M.D.
Chair
Institutional Review Board
Associate Dean for Research

REPORT OVERVIEW

Annual Award Number DAMD17-01-1-0334

Center Grant Overall Report

Project 1 Report

Project 2 Report

Project 3 Report

Core A Report

Core B Report

Core C Report

Code D Report

CENTER GRANT

"Genetic Factors in Breast Cancer: Center for
Interdisciplinary Biobehavioral Research"

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**Behavioral Center of Excellence Award:
Genetic Factors in Breast Cancer:
Center for Interdisciplinary Biobehavioral Research**

Principal Investigator: Dr. Dana H. Bovbjerg

INTRODUCTION:

The central goal of the Breast Cancer Behavioral Center of Excellence in the Ruttenberg Cancer Center of the Mount Sinai School of Medicine is to further our understanding of the impact of biobehavioral factors on genetic aspects of breast cancer in African American women. Several lines of research supported our choice of this theme, including: 1) Accumulating evidence indicates that what has been called the "biobehavioral model" or "biopsychosocial model" of health and disease may have considerable relevance for cancer generally, and for breast cancer in particular. Broadly stated, the premise of this model, now supported by substantial empirical evidence, is that what people think and feel affects the state of their health in at least two basic ways: by affecting their behavioral choices (e.g., alcohol consumption, screening decisions) and by affecting their biological processes (e.g., increased catecholamine levels with stress), each of which is controlled by the central nervous system. 2) Breast cancer in African American women is on average diagnosed at a younger age, with more advanced, aggressive tumors, and poorer prognosis. Although such findings raise the possibility of differences in the nature of the disease itself and attest to the importance of further study of underlying mechanisms responsible, particularly the role of hormonal factors, research is scant.

The Behavioral Center has three primary Objectives: 1) To support an integrated, interdisciplinary Program of Research consisting of three synergistic Research Projects each of which addresses an important issue in breast cancer genetic research with African American women that entails critical psychological or behavioral issues. Thus, our first purpose is to do outstanding research, with implications for our understanding of the etiology of breast cancer, as well as for our understanding of behavior per se. 2) To encourage the development of truly interdisciplinary thinking among the faculty involved in the Program of Research that can serve as a model for other institutions. Thus, our second purpose is to show by example, not only the utility of an interdisciplinary approach (synergy with Objective 1), but one approach that may facilitate its achievement - working together on an integrated project that addresses important issues of interest to all members of the research team. We propose to bridge the gap between biobehavioral research and epidemiologic approaches. 3) To facilitate the development of truly interdisciplinary perspectives among new investigators in breast cancer research. Thus, our third purpose is to provide both interdisciplinary training through both didactic and "hands-on" (synergy with Objective 1) research, as well as informal seminars (synergy with Objective 2) to outstanding young investigators

likely to represent the future of the field.

The Program of Research consists of three synergistic Projects (and four supporting Cores), each of which are reported upon separately below:

Project 1: Behavior, estrogen metabolism, and breast cancer risk: a molecular epidemiologic study. Ambrosone (PI) and colleagues will use a classic case-control design to examine the contribution of gene-environment interactions in breast cancer risk, specifically relations between early life stress, reproductive, hormonal and lifestyle factors and polymorphisms in enzymes involved in estrogen metabolism. In addition, this study will evaluate whether specific exposure, particularly early stage at menarche, as well as gene-environment interactions are related to earlier onset of breast cancer and more aggressive disease.

Project 2: Impact of culturally tailored counseling on psychobehavioral outcomes and BRCA decision making among women with breast cancer. Valdimarsdottir (PI) and colleagues will use a randomized clinical trial design to investigate the cognitive, emotional, and behavioral impact of providing culturally-tailored genetic counseling to those breast cancer patients (Cases) in Project 1 whose cancer is likely to have an inherited genetic basis. In addition, this study will examine if the benefits of the culturally tailored counseling will be greater for more traditional (less acculturated) African American women.

Project 3: Immune surveillance, stress, and inherited susceptibility to breast cancer: a psychobiological analysis of the healthy daughters of breast cancer patients. Bovbjerg (PI) and colleagues will use a longitudinal study design comparing the daughters of Cases in Project 1, to the daughters of Controls to examine the possibility that inherited deficits in immune surveillance mechanisms (e.g., natural killer cell activity, cytokine production) may account for the residual familial risk among daughters of patients whose cancers cannot be attributed to mutations in BRCA1 or BRCA2 genes. In addition, the study will explore the contribution of stress-induced immune modulation and inheritance of polymorphisms in the genes coding for two key cytokines, Interferon gamma and tumor necrosis factor alpha to the low surveillance phenotype.

These Projects synergize with one another both theoretically and practically. Each also is supported by the four Cores, which are dedicated to: A) Recruitment, Tracking, and Interviewing; B) Molecular Diagnostic and Research; C) Biostatistics and Data Management; and, D) Training.

Further understanding of the role of biobehavioral factors on the genetics of breast cancer in African American women may have profound implications for cancer prevention and control, as it may suggest novel strategies to reduce the threat posed by this disease to this underserved population.

BODY:

We have yet to receive official notification of approval of the HSRRB of the USAMRAA for all of the proposed three Projects, although our Mount Sinai Institutional Review Board has approved all for the past three years. Due to the extensive time required for this Army HSRRB review, we have fallen substantially behind our anticipated timeline for completion of the tasks listed in the Statements of Work for each of the Projects and Cores (as detailed for each Project and Core in separate sections below). In the absence of formal approval, we have continued to collect pilot data to enhance our readiness to make up for lost time once approval is obtained (see Project Reports, below). Although we have husbanded our resources, until we receive HSRRB approval we cannot determine whether we will be able to complete all the tasks associated with the Statements of Work as approved by peer review of submitted grant. Modification of those tasks may thus have to be requested next year, depending upon the outcome of our attempts to satisfy the requirements detailed by Dr. Pranulis for the HSRRB of the USAMRAA. While awaiting HSRRB approval, our second goal for the next year is to pilot all procedures and complete all Tasks that can be completed without such approval. We thus propose to be ready ourselves for immediate, effective, implementation of the proposed research once approval has been obtained.

KEY RESEARCH ACOMPLISHMENTS:

At this point in the research, with no approval by the HSRRB of the USAMRAA, results are not yet available. See detailed responses for each Project and Core below.

REPORTABLE OUTCOMES:

See detailed responses for each Project and Core below.

CONCLUSIONS:

With delays in approval by the HSRRB of the USAMRAA as yet, results are not available. During the next year we hope to be allowed by the HSRRB to initiate the full proposed research effort of the Center, which has been approved by our local IRB (Mt Sinai) for the past three years. The results of this research collected over the ensuing years will provide further understanding of the role of biobehavioral factors on the genetics of breast cancer in African American women. The proposed research may thus have profound implications for cancer prevention and control, as it may suggest novel strategies to reduce the threat posed by this disease to this important underserved population. See detailed responses for each Project and Core below.

PROJECT 1

"Behavior, estrogen metabolism, and breast cancer risk: a molecular epidemiologic study"

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Project 1: "Behavior, estrogen metabolism, and breast cancer risk: a molecular epidemiologic study"

Principal Investigator: Dr. Christine Ambrosone

INTRODUCTION:

African American women are more often diagnosed with breast cancer at an early age and have more aggressive disease. They are also more likely to experience menarche at an earlier age and to have higher estrogen levels. We hypothesize that earlier, more aggressive disease is related to earlier menarche and to lifetime hormonal exposures. Both breast cancer and early menarche are likely to be related to behavioral and reproductive factors, and to individual differences in hormone production and metabolism. In a case-control study, we will explore relationships between risk of breast cancer and a number of risk factors that will affect hormonal levels in women. We will also study how those factors may affect age at menarche. Because there is evidence that stressful events in early childhood result in early menarche, we will also evaluate the impact of childhood events on onset of menses. We also will study whether earlier menarche and factors related to greater lifetime exposure to estrogens will be associated with earlier age at breast cancer diagnosis and markers of more aggressive disease. Therefore, we will evaluate relationships between breast cancer risk and lifetime physical activity patterns, alcohol consumption, smoking, diet, weight and weight change throughout the life, early life events, and hormonal and reproductive factors, with data collected through an in-person interview. We will also evaluate genetic differences in hormone metabolism. The same factors, childhood body size, physical activity and early stressful events will also be evaluated in relation to age at menarche. In a case control study, we will identify African American women with incident breast cancer at hospitals in NYC with the largest referral patterns for African Americans and controls using random digit dialing. Both groups will be recruited (n=1600) by culturally sensitive breast cancer survivors. In-person interviews will be conducted and a blood specimen drawn. Statistical analyses will be performed to address each of the aims. There are few data to explain the earlier incidence of breast cancer and more aggressive disease among African Americans, and results from this study will elucidate the probable link between breast cancer risk, early age at menarche and hormonal milieu, and the factors that predict them. This molecular epidemiologic study will take into account the role of behavioral factors and early childhood lifetime events in breast cancer etiology, which has not been explored to date.

BODY:

Statement of Work

Task 1. Start-up and organizational tasks, Months 1–6:

- a. Develop study protocols for ascertainment of cases at each site
- b. Identify, hire, and train interviewers
- c. Pilot test study questionnaire and refine accordingly

- d. Develop other study-related instruments and data collection forms
- e. Design database for subject tracking and data entry of questionnaire and other data collection forms, incorporate logic and validity checks

In Year 3 of the grant we continued to refine supporting study materials and strengthen the infrastructure of the study as per our proposed statement of work while we waited for HSRRB approval to conduct the study. We modified the protocol, informed consent documents and study-related instruments and forms to facilitate data collection and tracking based on recommendations from HSRRB and to be in compliance with HIPAA. We were waiting to receive approval from HSRRB for the final protocol and consent before submitting to collaborating hospitals for IRB approval at those sites. We submitted all final documents to the HSRRB in the previous year. Documents were received by the HSRRB on July 24, 2003. We received approval from the HSRRB on April 16th, 2004. We also have identified and contacted physicians at additional hospitals that we would like to include as participating sites. The study questionnaire has been modified and bound. Materials for the training of interviewers and maintenance of data quality have been updated. The textual content for participant letters and a brochure introducing the study has been finalized and approved by IRB review. Four interviewers were hired and trained. A database in ACCESS[®] has been designed and validated for subject tracking.

Task 2. Identify and recruit study subjects, Months 7-42

- a. Identify ~1,400 incident breast cancer cases at participating hospitals through daily or weekly contact with institutions or private doctor's offices
- b. Verify case eligibility and obtain physician consent to contact cases
- c. Identify ~1,200 controls through the use of random digit dialing for those 20 to 64 years of age and Health Care Finance Administration rosters for those 65 to 74 years of age
- d. Assign unique identification number to each potential participant to be used on all study materials (to ensure confidentiality, personal identifiers will be kept separate from all other data)
- e. Mail introductory letter
- f. Telephone contact of potential subjects
 - 1) Introduce study
 - 2) Schedule in-person interview at a time and place that is convenient for participant

Task 3. Conduct in-person interview, Months 7-42

- a. Obtain informed consent and signed medical release form
- b. Interviewer administers:
 - 1) Main questionnaire
 - 2) Block food frequency questionnaire
- c. Measure height, weight, waist and hip circumference
- d. Collect blood specimens

As of July 2002, the Centers for Medicare & Medicaid Services (CMS), formerly the Health Care Finance Administration (HCFA) ceased the release of the Medicare Names and Addresses files to researchers. CMS has imposed a moratorium on the release of these files until they reevaluate their procedures for providing this information in accordance with HIPAA. Since CMS lists are considered the most complete enumeration available for women over 65 years of age in the United States, and random selection from this list can be specifically tailored to create a representative control population, loss of this source of controls has caused us to alter our study design. Because the focus of the protocol is on early age of onset in African American women, we have revised the age range eligibility from 20 to 74 years of age to 20 to 64 years of age. Thus, controls will only be identified through RDD. This revision will not affect our study hypothesis, and based on power analyses, we will still enroll 800 cases and 800 controls, although they will all be under age 65.

Since receiving HSRRB approval on April 16th, 2004, we have been working to put the approved protocol through the IRBs of collaborating hospitals. We have also modified our methodology for patient ascertainment to comply with newer IRB and HIPAA regulations. Because of patient confidentiality issues, we can no longer receive identifiers from physicians. Rather, we will communicate regularly with physician offices and when patients are scheduled who the clinicians feel would be eligible for the study, a research assistant (RA) will be informed, and be present in the clinic on those days. The physicians then receive patient permission for referral to our RA, who will inform potential participants about the study. Alternatively, physicians will refer eligible patients who have granted permission to be contacted by a member of our study team. Contact information for patients who agree to participate in the study will be given to interviewers, who schedule appointments to conduct the informed consent process, administer the interview, perform anthropometry measurements, and collect a blood specimen. Interviews will be conducted at either the patient's home or at the hospital, depending upon their preference. To date, we have not yet enrolled patients, as IRB approvals at the hospitals are still pending.

We have initiated identifying potential controls through random digit dialing. Those who agree to be contacted are sent a letter and brochure and a call is made subsequently to provide further information regarding the study and to schedule an appointment. The interview process will be conducted in the same manner as that outlined for cases.

Task 4. Interviewer quality control, Months 7-42

- a. Review the first batch of interviews (n~10) by each interviewer and provide feedback to each interviewer
- b. Review all interview-related materials for completeness and internal consistency
- c. Provide feedback to interviewers on a regular basis
- d. Call back a ten percent sample of both cases and controls to validate questionnaire administration and key information collected

- Task 5. Abstract pathology and breast cancer treatment information, Months 7-43:
- Abstract tumor specific characteristics such as tumor size, stage, grade, nodal involvement, and hormone receptor from pathology reports
 - Abstract breast cancer related treatment including surgery and prescribed adjuvant therapies from medical records and physicians' patient files
- Task 6. Data entry, Months 7-44
- Information obtained throughout the study (participant contact information, main questionnaire, pathology and treatment abstract form, body size measurements) will be entered as collected
 - All data will be double key entered to ensure accuracy
- Task 7. Food frequency questionnaire data processing, Months 7-44:
- Food frequency questionnaires are sent for scanning and nutrient analysis
 - Data files containing raw data and nutrient information are returned to Mount Sinai on a disk

We have not begun to review questionnaires with interviewers or to abstract medical record information because enrollment of patients is pending due to delays in processing by HSRRB. Our plan is to review records after women have completed treatment, which should be at least 6 months after diagnosis. Data will be entered under the direction of the Statistical Core, after questionnaires are reviewed and coded by two RAs.

Task 8. Perform genotyping (Core B) Months 24-42:

No specimens have been collected to date.

- Task 9. Data cleaning, statistical analysis, and manuscript preparation, Months 43-48:
- Write logic checks to determine out-of-range variable values and inconsistencies
 - Comprehensive analyses of data
 - Drafts of manuscripts
 - Manuscripts submitted

Please note that we only recently obtained approval from HSRRB. We, therefore, propose to modify the timeline for subsequent tasks. We were recently awarded funding by NCI to recruit Caucasians to compare to the African-American women recruited under this award. The protocol and study questionnaire for these awards are essentially the same. We, therefore, anticipate in the coming year amending the protocol and consent forms for this study to include Caucasians so that they maybe recruited simultaneously.

KEY RESEARCH ACCOMPLISHMENTS:

- Refine infrastructure for molecular epidemiologic study (questionnaire, protocols and equipment for blood processing and specimen banking, interviewing, hiring, and training interviewers, databases for participant tracking). Identify eligible controls; conduct interviews, process and bank specimens; begin DNA extractions; code questionnaires and enter data.

REPORTABLE OUTCOMES:

Additional grants have been received based upon this funded study.

Source: DOD (Funded)

Grant Number: BC011079

Project Title: Immune Surveillance, Cytokines and Breast Cancer Risk: Genetic and Psychological Influences in African American Women

Project Period: 7/01/02-6/30/07 Total Direct Costs: \$624,946

P.I.: D. Bovbjerg

Source: K07/NIH (Funded)

Grant Number: CA93447-01A1

Project Title: Energy Balance & Breast Cancer in African Americans

Project Period: 9/30/02-9/29/07 Total Direct Costs: \$666,225

P.I.: J. Britton

Source: NCI (Funded)

Grant Number: R01 CA 100598

Project Title: Race & Risk Factors for Early/Aggressive Breast Cancer

Project Period: 4/01/04-3/30/09 Total Direct Costs (Yr 1): \$437,672

P.I.: C. Ambrosone

CONCLUSIONS:

At this time, we are preparing to enroll participants into the study, due to the delays in obtaining HSRRB approval. No analyses have been performed. Thus, no findings can be reported at this time.

REFERENCES:

None

APPENDICES:

Main Questionnaire

PROJECT 1 APPENDIX

MAIN QUESTIONNAIRE

December 31, 2003

Study ID#: _____



WOMEN'S CIRCLE OF HEALTH

Interviewer ID _____

Date of interview ____/____/____
Month Day Year

Time interview began ____:____ am/pm

Time interview ended ____:____ am/pm

Breaks: _____

Length of interview: _____

Has reference date changed from diagnosis date?

☐ Yes ☐ No ☐ DK

Has participant previously been consented?

☐ Yes ☐ No ☐ DK

Was blood drawn prior to date of interview?

☐ Yes ☐ No ☐ DK

Does participant want study results?

☐ Yes ☐ No ☐ DK

Was a continuation booklet used?

☐ Yes ☐ No ☐ DK

Has participant agreed to be contacted for other studies?

☐ Yes ☐ No ☐ DK

Case ☐ 1

Control ☐ 2

	Date	Initials
Interviewer:		
Reviewed by:		
Coded 1:		
Coded 2:		

A. DEMOGRAPHICS SECTION

Interviewer, please enter the reference date
in the following format: **MMDDYYYY**, e.g. April 4,
1950 = '04041950'

____/____/____
Month Day Year

CASES ONLY:

When did a doctor first tell you that you had breast cancer?

____/____/____
Month Day Year

At what hospital were you 1st diagnosed with breast cancer? _____

What was the name of the doctor who 1st diagnosed your breast cancer? _____

If self-reported date is EARLIER than assigned RD then use as RD throughout interview

Since many people have never been in an interview exactly like this, let me start by explaining to you how it works. In this interview I am going to read you a set of questions exactly as they are worded, so that every person in the study is answering the same questions. If at any time during the interview you are not clear about what is wanted, be sure to ask me. Also, it is very important that your answers be accurate and complete. Please take as much time as you need. If there are any questions that you are uncomfortable with, please feel free to tell me and we will skip them. Throughout this interview we are interested in things you did before (RD). This is the date that you became eligible for this health study. I'll begin by asking you some questions about your background.

A1. What is your date of birth?

____/____/____
Month Day Year

99 ☐ DK/Refused

A2. What is your current age?

____ age

99 ☐ DK/Refused

A3. In what U.S. state or foreign country were you born?

(Name of state or country)

99 ☐ DK/Refused

If participant was born in foreign country ask A4, otherwise go to A5.

A4. How old were you when you moved to the U.S.?

____ age

99 ☐ DK/Refused

A5. Do you consider yourself to be of Latina or Hispanic origin?

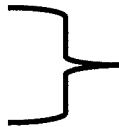
- 1 ☐ Yes
 2 ☐ No
 9 ☐ DK/Refused

**A5a. Do you consider yourself to be any of the following?
(Check all that apply)**

- 01 ☐ Mexican/Mexican American/Chicano
 02 ☐ Puerto Rican
 03 ☐ Cuban
 04 ☐ Caribbean or West Indian
 05 ☐ Dominican
 06 ☐ Other (please specify): _____
 99 ☐ DK/Refused

A6. What is your race? (Check all that apply.)

- 01 ☐ White
 02 ☐ Black/African American
 03 ☐ Black/African
 04 ☐ Black-West Indian / Caribbean
 05 ☐ Black-Other
 06 ☐ American Indian or Alaska Native
 07 ☐ Asian Indian
 08 ☐ Chinese
 09 ☐ Filipino
 10 ☐ Korean
 11 ☐ Vietnamese
 12 ☐ Other Asian
 13 ☐ Native Hawaiian
 14 ☐ Guamanian or Chamorro
 15 ☐ Samoan
 16 ☐ Other Pacific Islander
 17 ☐ Some other race (specify): _____
 99 ☐ DK/Refused



Eligible for Project 2
If Case, give Project 2 (TACT) brochure
(see criteria for Project 2 consent)

Show
Card

A6a. Interviewer: If participant does not choose one category please mark your assessment of race.

- 01 ☐ White
 02 ☐ Black
 03 ☐ Asian/Pacific Islander
 04 ☐ Other: _____

A7. What was the highest grade of school that you completed?

- 1 ☐ Less than 8th grade
 2 ☐ 8th to 11th grade
 3 ☐ High school graduate or equivalent (GED)
 4 ☐ Technical or vocational school
 5 ☐ Some college
 6 ☐ College graduate
 7 ☐ Post-graduate degree
 9 ☐ DK/Refused

Show
Card

A8. Are you adopted?

- 1 ☐ Yes
 2 ☐ No
 9 ☐ DK/Refused

A9. Can you answer questions about your blood relatives?

- 1 ☐ Yes
 2 ☐ No (C1)

In the next set of questions I will ask you about your parents and grandparents.

A10. In what U.S. state or foreign country was your MOTHER born?

 (Name of state or country)

99 ☐ DK/Refused

A11. Is your MOTHER of Latina or Hispanic origin?

- 1 ☐ Yes
 2 ☐ No
 9 ☐ DK/Refused

A11a. Does she consider herself to be any of the following?
 (Check all that apply)

- 01 ☐ Mexican/Mexican American/Chicano
 02 ☐ Puerto Rican
 03 ☐ Cuban
 04 ☐ Caribbean or West Indian
 05 ☐ Dominican
 06 ☐ Other (please specify): _____
 99 ☐ DK/Refused

A12. What is your MOTHER'S race? (Check all that apply)

- 01 ☐ White
 02 ☐ Black/African American
 03 ☐ Black/African
 04 ☐ Black-West Indian / Caribbean
 05 ☐ Black-Other
 06 ☐ American Indian or Alaska Native
 07 ☐ Asian Indian
 08 ☐ Chinese
 09 ☐ Filipino
 10 ☐ Korean
 11 ☐ Vietnamese
 12 ☐ Other Asian
 13 ☐ Native Hawaiian
 14 ☐ Guamanian or Chamorro
 15 ☐ Samoan
 16 ☐ Other Pacific Islander
 17 ☐ Some other race (specify): _____
 99 ☐ DK/Refused

Show
Card

A13. What was the highest grade of school your MOTHER completed?

- 1 ☐ Less than 8th grade
 2 ☐ 8th to 11th grade
 3 ☐ High school graduate or equivalent (GED)
 4 ☐ Technical or vocational school
 5 ☐ Some college
 6 ☐ College graduate
 7 ☐ Post-graduate degree
 9 ☐ DK/Refused

Show
Card

A14. In what country was your MOTHER'S MOTHER (maternal grandmother) born?

(Name of country)

99 ☐ DK/Refused

A15. In what country was your MOTHER'S FATHER (maternal grandfather) born?

(Name of country)

99 ☐ DK/Refused

A16. In what U.S. state or foreign country was your FATHER born?

(Name of country)

99 ☐ DK/Refused

A17. Is your FATHER of Latino or Hispanic origin?

- 1 ☐ Yes
 2 ☐ No
 9 ☐ DK/Refused

**A17a. Does he consider himself to be any of the following?
(Check all that apply)**

- 01 ☐ Mexican/Mexican American/Chicano
 02 ☐ Puerto Rican
 03 ☐ Cuban
 04 ☐ Caribbean or West Indian
 05 ☐ Dominican
 06 ☐ Other (please specify): _____
 99 ☐ DK/Refused

Card

A18. What is your FATHER'S race? (Check all that apply)

- 01 ☐ White
 02 ☐ Black/African American
 03 ☐ Black/African
 04 ☐ Black-West Indian / Caribbean
 05 ☐ Black-Other
 06 ☐ American Indian or Alaska Native
 07 ☐ Asian Indian
 08 ☐ Chinese
 09 ☐ Filipino
 10 ☐ Korean
 11 ☐ Vietnamese
 12 ☐ Other Asian
 13 ☐ Native Hawaiian
 14 ☐ Guamanian or Chamorro
 15 ☐ Samoan
 16 ☐ Other Pacific Islander
 17 ☐ Some other race (specify): _____
 99 ☐ DK/Refused

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A19. What was the highest grade of school that your FATHER completed?

- 1 ☐ Less than 8th grade
 2 ☐ 8th to 11th grade
 3 ☐ High school graduate or equivalent (GED)
 4 ☐ Technical or vocational school
 5 ☐ Some college
 6 ☐ College graduate
 7 ☐ Post-graduate degree
 9 ☐ DK/Refused

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A20. In what country was your FATHER'S MOTHER (paternal grandmother) born?

 (Name of country)

99 ☐ DK/Refused

A21. In what country was your FATHER'S FATHER (paternal grandfather) born?

 (Name of country)

99 ☐ DK/Refused

B. FAMILY HEALTH HISTORY

In this section of the questionnaire I would like to ask you about the health history of your blood relatives. This would include your parents, siblings and children. I am interested in both living and deceased members of your family, but only full-blood relatives.

B1. Is your father still living?

- 1 ☐ Yes _____ → B1a. How old is he? _____ age
- 2 ☐ No _____ → B1b. How old was he or what year was it when he died?
- 9 ☐ DK/Refused _____ age OR _____ year

B2. (Has/was) your father ever (been) diagnosed with cancer?	B3. What type(s) of cancer did he have?	B4. How old was he when this cancer was first diagnosed?
1 <input type="checkbox"/> Yes _____ →	a. _____	a. _____ age
2 <input type="checkbox"/> No (B5)	b. _____	b. _____ age
9 <input type="checkbox"/> DK/Refused (B5)	c. _____	c. _____ age

B5. Is your mother still living?

- 1 ☐ Yes _____ → B5a. How old is she? _____ age
- 2 ☐ No _____ → B5b. How old was she or what year was it when she died?
- 9 ☐ DK/Refused _____ age OR _____ year

B6. (Has/was) your mother ever (been) diagnosed with cancer?	B7. What type(s) of cancer did she have?	B8. How old was she when this cancer was first diagnosed?
1 <input type="checkbox"/> Yes _____ →	a. _____	a. _____ age
2 <input type="checkbox"/> No (B9)	b. _____	b. _____ age
9 <input type="checkbox"/> DK/R (B9)	c. _____	c. _____ age

Now I would like to ask about your full brothers and sisters, that is, those with whom you share both birth mother and father. Please include brothers and sisters who are living or deceased, but do not include adopted, foster, half or step brothers or sisters.

B9. How many full brothers do you have? _____ number of brothers

B10. How many full sisters do you have? _____ number of sisters

Now let's start with the oldest among your sibling(s).

B11. What is the first name of your (oldest/next) sibling?	B12. Is (name) a male or female?	B13. Is (he/she) still living?	B14. How old [is (he/she)/was (he/she) when (he/she) died]?	B15. [Has/was] (he/she) ever (been) diagnosed with cancer?	B16. What type(s) of cancer did he/she have?	B17. How old was (he/she) when this cancer was first diagnosed?
a	1 <input type="checkbox"/> Male 2 <input type="checkbox"/> Female	1 <input type="checkbox"/> Yes 2 <input type="checkbox"/> No 9 <input type="checkbox"/> DK/R	____ age	1 <input type="checkbox"/> Yes _____ 2 <input type="checkbox"/> No (b) 9 <input type="checkbox"/> DK/Refused (b)	a. _____ b. _____ c. _____	a. ____ age b. ____ age c. ____ age
b	1 <input type="checkbox"/> Male 2 <input type="checkbox"/> Female	1 <input type="checkbox"/> Yes 2 <input type="checkbox"/> No 9 <input type="checkbox"/> DK/R	____ age	1 <input type="checkbox"/> Yes _____ 2 <input type="checkbox"/> No (c) 9 <input type="checkbox"/> DK/Refused (c)	a. _____ b. _____ c. _____	a. ____ age b. ____ age c. ____ age
c	1 <input type="checkbox"/> Male 2 <input type="checkbox"/> Female	1 <input type="checkbox"/> Yes 2 <input type="checkbox"/> No 9 <input type="checkbox"/> DK/R	____ age	1 <input type="checkbox"/> Yes _____ 2 <input type="checkbox"/> No (d) 9 <input type="checkbox"/> DK/Refused (d)	a. _____ b. _____ c. _____	a. ____ age b. ____ age c. ____ age
d	1 <input type="checkbox"/> Male 2 <input type="checkbox"/> Female	1 <input type="checkbox"/> Yes 2 <input type="checkbox"/> No 9 <input type="checkbox"/> DK/R	____ age	1 <input type="checkbox"/> Yes _____ 2 <input type="checkbox"/> No (e) 9 <input type="checkbox"/> DK/Refused (e)	a. _____ b. _____ c. _____	a. ____ age b. ____ age c. ____ age
e	1 <input type="checkbox"/> Male 2 <input type="checkbox"/> Female	1 <input type="checkbox"/> Yes 2 <input type="checkbox"/> No 9 <input type="checkbox"/> DK/R	____ age	1 <input type="checkbox"/> Yes _____ 2 <input type="checkbox"/> No (f) 9 <input type="checkbox"/> DK/Refused (f)	a. _____ b. _____ c. _____	a. ____ age b. ____ age c. ____ age

B11. What is the first name of your (oldest/next) sibling?	B12. Is (name) a male or female?	B13. Is (he/she) still living?	B14. How old [is (he/she)/ was (he/she) when (he/she) died]?	B15. [Has/was] (he/she) ever (been) diagnosed with cancer?	B16. What type(s) of cancer did he/she have?	B17. How old was (he/she) when this cancer was first diagnosed?
f	1 <input type="checkbox"/> Male 2 <input type="checkbox"/> Female	1 <input type="checkbox"/> Yes 2 <input type="checkbox"/> No 9 <input type="checkbox"/> DK/R	____ age	1 <input type="checkbox"/> Yes _____ 2 <input type="checkbox"/> No _____ (g) 9 <input type="checkbox"/> DK/Refused (g)	a. _____ b. _____ c. _____	a. _____ age b. _____ age c. _____ age
g	1 <input type="checkbox"/> Male 2 <input type="checkbox"/> Female	1 <input type="checkbox"/> Yes 2 <input type="checkbox"/> No 9 <input type="checkbox"/> DK/R	____ age	1 <input type="checkbox"/> Yes _____ 2 <input type="checkbox"/> No _____ (h) 9 <input type="checkbox"/> DK/Refused (h)	a. _____ b. _____ c. _____	a. _____ age b. _____ age c. _____ age
h	1 <input type="checkbox"/> Male 2 <input type="checkbox"/> Female	1 <input type="checkbox"/> Yes 2 <input type="checkbox"/> No 9 <input type="checkbox"/> DK/R	____ age	1 <input type="checkbox"/> Yes _____ 2 <input type="checkbox"/> No _____ (i) 9 <input type="checkbox"/> DK/Refused (i)	a. _____ b. _____ c. _____	a. _____ age b. _____ age c. _____ age
i	1 <input type="checkbox"/> Male 2 <input type="checkbox"/> Female	1 <input type="checkbox"/> Yes 2 <input type="checkbox"/> No 9 <input type="checkbox"/> DK/R	____ age	1 <input type="checkbox"/> Yes _____ 2 <input type="checkbox"/> No _____ (j) 9 <input type="checkbox"/> DK/Refused (j)	a. _____ b. _____ c. _____	a. _____ age b. _____ age c. _____ age
j	1 <input type="checkbox"/> Male 2 <input type="checkbox"/> Female	1 <input type="checkbox"/> Yes 2 <input type="checkbox"/> No 9 <input type="checkbox"/> DK/R	____ age	1 <input type="checkbox"/> Yes _____ 2 <input type="checkbox"/> No _____ (B18) 9 <input type="checkbox"/> DK/Refused (B18)	a. _____ b. _____ c. _____	a. _____ age b. _____ age c. _____ age

If more than 10 siblings check here _____ and add additional pages.

Now I would like to ask you about your children. Again, please include only your biological children, whether they are living or deceased, but not adopted, foster or step-children.

B18. How many biological children have you had?

If no children, B26

B19. What is the first name of your (oldest/next) child?	B20. Is (he/she) male or female?	B21. Is (he/she) still living?	B22. How old [is (he/she)/was (he/she) [when (he/she) died]]?	B23. [Has/was] (he/she) ever (been) diagnosed with cancer?	B24. What type(s) of cancer did he/she have?	B25. How old was (he/she) when this cancer was first diagnosed?
a	1 <input type="checkbox"/> Male 2 <input type="checkbox"/> Female	1 <input type="checkbox"/> Yes 2 <input type="checkbox"/> No 9 <input type="checkbox"/> DK/R	____ age	1 <input type="checkbox"/> Yes 2 <input type="checkbox"/> No 9 <input type="checkbox"/> DK/Refused (b)	a. _____ b. _____ c. _____	a. _____ age b. _____ age c. _____ age
b	1 <input type="checkbox"/> Male 2 <input type="checkbox"/> Female	1 <input type="checkbox"/> Yes 2 <input type="checkbox"/> No 9 <input type="checkbox"/> DK/R	____ age	1 <input type="checkbox"/> Yes 2 <input type="checkbox"/> No 9 <input type="checkbox"/> DK/Refused (c)	a. _____ b. _____ c. _____	a. _____ age b. _____ age c. _____ age
c	1 <input type="checkbox"/> Male 2 <input type="checkbox"/> Female	1 <input type="checkbox"/> Yes 2 <input type="checkbox"/> No 9 <input type="checkbox"/> DK/R	____ age	1 <input type="checkbox"/> Yes 2 <input type="checkbox"/> No 9 <input type="checkbox"/> DK/Refused (d)	a. _____ b. _____ c. _____	a. _____ age b. _____ age c. _____ age
d	1 <input type="checkbox"/> Male 2 <input type="checkbox"/> Female	1 <input type="checkbox"/> Yes 2 <input type="checkbox"/> No 9 <input type="checkbox"/> DK/R	____ age	1 <input type="checkbox"/> Yes 2 <input type="checkbox"/> No 9 <input type="checkbox"/> DK/Refused (e)	a. _____ b. _____ c. _____	a. _____ age b. _____ age c. _____ age

									c. ____ age
e	1 <input type="checkbox"/> Male 2 <input type="checkbox"/> Female	1 <input type="checkbox"/> Yes 2 <input type="checkbox"/> No 9 <input type="checkbox"/> DK/R	____ age	1 <input type="checkbox"/> Yes 2 <input type="checkbox"/> No 9 <input type="checkbox"/> DK/Refused (f)	____ age	a. ____ b. ____ c. ____	a. ____ b. ____ c. ____	a. ____ b. ____ c. ____	a. ____ age b. ____ age c. ____ age

	B19. What is the first name of your (oldest/next) child?	B20. Is (he/she) male or female?	B21. Is (he/she) still living?	B22. How old [is (he/she)/was (he/she) [when (he/she) died]? ____ age	B23. [Has/was] (he/she) ever (been) diagnosed with cancer? 1 <input type="checkbox"/> Yes 2 <input type="checkbox"/> No 9 <input type="checkbox"/> DK/Refused (g)	B24. What type(s) of cancer did he/she have? a. ____ b. ____ c. ____	B25. How old was (he/she) when this cancer was first diagnosed? a. ____ age b. ____ age c. ____ age
f		1 <input type="checkbox"/> Male 2 <input type="checkbox"/> Female	1 <input type="checkbox"/> Yes 2 <input type="checkbox"/> No 9 <input type="checkbox"/> DK/R	____ age	1 <input type="checkbox"/> Yes 2 <input type="checkbox"/> No 9 <input type="checkbox"/> DK/Refused (g)	a. ____ b. ____ c. ____	a. ____ age b. ____ age c. ____ age
g		1 <input type="checkbox"/> Male 2 <input type="checkbox"/> Female	1 <input type="checkbox"/> Yes 2 <input type="checkbox"/> No 9 <input type="checkbox"/> DK/R	____ age	1 <input type="checkbox"/> Yes 2 <input type="checkbox"/> No 9 <input type="checkbox"/> DK/Refused (h)	a. ____ b. ____ c. ____	a. ____ age b. ____ age c. ____ age
h		1 <input type="checkbox"/> Male 2 <input type="checkbox"/> Female	1 <input type="checkbox"/> Yes 2 <input type="checkbox"/> No 9 <input type="checkbox"/> DK/R	____ age	1 <input type="checkbox"/> Yes 2 <input type="checkbox"/> No 9 <input type="checkbox"/> DK/Refused (i)	a. ____ b. ____	a. ____ age b. ____ age

						c. _____ age _____
i	1 <input type="checkbox"/> Male 2 <input type="checkbox"/> Female	1 <input type="checkbox"/> Yes 2 <input type="checkbox"/> No 9 <input type="checkbox"/> DK/R	____ age	1 <input type="checkbox"/> Yes 2 <input type="checkbox"/> No 9 <input type="checkbox"/> DK/Refused	a. _____ b. _____ c. _____	a. _____ age b. _____ age c. _____ age
j	1 <input type="checkbox"/> Male 2 <input type="checkbox"/> Female	1 <input type="checkbox"/> Yes 2 <input type="checkbox"/> No 9 <input type="checkbox"/> DK/R	____ age	1 <input type="checkbox"/> Yes 2 <input type="checkbox"/> No 9 <input type="checkbox"/> DK/Refused	a. _____ b. _____ c. _____	a. _____ age b. _____ age c. _____ age

If any living daughters are > 18 years old then eligible for Project 3, complete contact form and check box on post-interview checklist!

B26. Have any of your other relatives, such as grandparents, aunts, uncles, cousins, or half-siblings, been diagnosed with breast or ovarian cancer?

- 1 ☐ Yes
 2 ☐ Yes, possibly
 3 ☐ No (C1)
 9 ☐ DK/Refused (C1)

B27. As far as you know, which relatives were diagnosed with breast cancer?
 (Check all that apply)

01 <input type="checkbox"/> None	
02 <input type="checkbox"/> Mother's mother	At what age was she diagnosed? _____ age
03 <input type="checkbox"/> Father's mother	At what age was he diagnosed? _____ age
04 <input type="checkbox"/> Mother's sister(s)	a. How many with breast cancer? _____ At what age(s) (was she/were they) diagnosed? _____ age _____ age _____ age _____ age
05 <input type="checkbox"/> Father's sister(s)	b. How many with breast cancer? _____ At what age(s) (was she/were they) diagnosed? _____ age _____ age _____ age _____ age
06 <input type="checkbox"/> My maternal half sister(s)	c. How many with breast cancer? _____ At what age(s) (was she/were they) diagnosed? _____ age _____ age _____ age _____ age
07 <input type="checkbox"/> My paternal half sister(s)	d. How many with breast cancer? _____ At what age(s) (was she/were they) diagnosed? _____ age _____ age _____ age _____ age
08 <input type="checkbox"/> Maternal male relatives	e. How many with breast cancer? _____ At what age(s) (was he/were they) diagnosed? _____ age _____ age _____ age _____ age
09 <input type="checkbox"/> Paternal male relatives	f. How many with breast cancer? _____ At what age(s) (was he/were they) diagnosed? _____ age _____ age _____ age _____ age
10 <input type="checkbox"/> Other relative(s)	g. Please specify who: _____ _____ At what age(s) (was she or he /were they) diagnosed? _____ age _____ age _____ age _____ age
99 <input type="checkbox"/> DK/Refused	

B28. As far as you know, which relatives were diagnosed with ovarian cancer?
(Check all that apply)

01 <input type="checkbox"/> None	
02 <input type="checkbox"/> Mother's mother	At what age was she diagnosed? _____ age
03 <input type="checkbox"/> Father's mother	At what age was she diagnosed? _____ age
04 <input type="checkbox"/> Mother's sister(s)	a. How many with ovarian cancer? _____ At what age(s) (was she/were they) diagnosed? _____ age _____ age _____ age _____ age _____ age
05 <input type="checkbox"/> Father's sister(s)	b. How many with ovarian cancer? _____ At what age(s) (was she/were they) diagnosed? _____ age _____ age _____ age _____ age _____ age
06 <input type="checkbox"/> My maternal half sister(s)	c. How many with ovarian cancer? _____ At what age(s) (was she/were they) diagnosed? _____ age _____ age _____ age _____ age _____ age
07 <input type="checkbox"/> My paternal half sister(s)	d. How many with ovarian cancer? _____ At what age(s) (was she/were they) diagnosed? _____ age _____ age _____ age _____ age _____ age
08 <input type="checkbox"/> Other relative(s)	e. Please specify who: _____ _____ At what age(s) (was she/were they) diagnosed? _____ age _____ age _____ age _____ age _____ age
99 <input type="checkbox"/> DK/Refused	

C. PRENATAL EXPOSURES

Now I would like to ask you some information about when your mother was pregnant with you.

C1. Were you a twin or multiple birth?

- 1 ☐ Yes, twin (C2)
- 2 ☐ Yes, multiple (C3)
- 3 ☐ No (C5)
- 9 ☐ DK/Refused (C5)

C2. Was your twin female?

- 1 ☐ Yes (C4)
- 2 ☐ No (C5)
- 9 ☐ DK/Refused (C5)

C3. Were any of your siblings in this multiple birth female?

- 1 ☐ Yes (C4)
- 2 ☐ No (C5)
- 9 ☐ DK/Refused (C5)

C4. Do you have an identical sibling?

- 1 ☐ Yes
- 2 ☐ No
- 9 ☐ DK/Refused

C5. Do you know how much you weighed when you were born?

- 1 ☐ Yes
- 2 ☐ No
- 9 ☐ DK/Refused

C5a. What was your weight?

_____ pounds _____ ounces

If birthweight is known, skip to question C8.

C6. Do you think you weighed less than 5 ½ pounds?

- 1 ☐ Yes (C8)
- 2 ☐ No
- 9 ☐ DK/Refused

C7. Do you think you weighed 9 pounds or more?

- 1 ☐ Yes
- 2 ☐ No
- 9 ☐ DK/Refused

C8. As far as you know, did your mother breastfeed you?

- 1 ☐ Yes _____ →
2 ☐ Yes probably/possibly
3 ☐ No
9 ☐ DK/Refused

C8a. How long did she breastfeed you?

_____ months
99 ☐ DK/Refused

C9. As far as you know, did your mother smoke when she was pregnant with you?

- 1 ☐ Yes
2 ☐ Yes probably/possibly
3 ☐ No
9 ☐ DK/Refused

D. MENSTRUAL HISTORY

Now I would like to ask you some questions about your own reproductive and medical history.

D1. Approximately how old were you when you had your first menstrual period?

____ . ____ age

99 ☐ DK/Refused

D2. Did you have your period during the 12 months before (RD)?

- 1 ☐ Yes
2 ☐ No
9 ☐ DK/Refused

D3. How would you characterize your menstrual status during the 12 months before (RD)?

- 01 ☐ Still having periods and **not** going through menopause or the change of life
02 ☐ Still having periods but possibly beginning menopause or the change of life
03 ☐ Still having periods and on hormone replacement therapy
04 ☐ Going through menopause or the change of life
05 ☐ Postmenopausal
06 ☐ Was pregnant
07 ☐ Other (specify): _____
99 ☐ DK/Refused

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D4. During what month and year or at what age did you have your last period?

____ / ____ OR ____ age
Month Year

Check answer to question D2, if respondent answered Yes or DK/R, skip to question E1. If No, then ask:

D5. Please tell me all the reasons your menstrual periods stopped. (Check all that apply.)

- 01 ☐ They stopped naturally
02 ☐ I had a hysterectomy
03 ☐ I had both ovaries removed
04 ☐ I was having or had radiation treatment/chemotherapy
05 ☐ I was nursing
06 ☐ I was taking hormones
07 ☐ Other (specify): _____
08 ☐ I had one ovary removed
99 ☐ DK/Refused

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D6. Around the time your periods stopped, how much did you weigh?

____ pounds OR ____ kilograms

999 ☐ DK/Refused

E. PREGNANCY HISTORY

Now I would like to ask you about your pregnancy history.

E1. During your lifetime, how many times have you been pregnant? Be sure to count this pregnancy if you are currently pregnant.

_____ Pregnancies (Use 00 for never pregnant and skip to F1)

E2. Are you currently pregnant?

1 ☐ Yes _____ →

E2a. How many weeks or months?

_____ weeks or _____ months

2 ☐ No

If this is the participant's first and only pregnancy skip to E7

	E3. What was the outcome of your (first/next) pregnancy?	E4. How many weeks or months did this pregnancy last?	E5. In what month and year did this pregnancy end?	E6. Did you breast-feed this baby? If so, for how long?
a	1 <input type="checkbox"/> Single live birth 2 <input type="checkbox"/> Multiple birth, any living	_____ Months Or _____ Weeks	_____ / _____ Month Year	1 <input type="checkbox"/> Yes E6a. How long? ↓ _____ Months
	3 <input type="checkbox"/> Multiple birth, none living 4 <input type="checkbox"/> Stillbirth 5 <input type="checkbox"/> Spontaneous miscarriage 6 <input type="checkbox"/> Induced abortion 7 <input type="checkbox"/> Tubal or ectopic pregnancy 8 <input type="checkbox"/> Other (specify): _____	_____ Months Or _____ Weeks	_____ / _____ Month Year	2 <input type="checkbox"/> No 9 <input type="checkbox"/> DK/Refused
b	1 <input type="checkbox"/> Single live birth 2 <input type="checkbox"/> Multiple birth, any living	_____ Months Or _____ Weeks	_____ / _____ Month Year	1 <input type="checkbox"/> Yes E6b. How long? ↓ _____ Months
	3 <input type="checkbox"/> Multiple birth, none living 4 <input type="checkbox"/> Stillbirth 5 <input type="checkbox"/> Spontaneous miscarriage 6 <input type="checkbox"/> Induced abortion 7 <input type="checkbox"/> Tubal or ectopic pregnancy 8 <input type="checkbox"/> Other (specify): _____	_____ Months Or _____ Weeks	_____ / _____ Month Year	2 <input type="checkbox"/> No 9 <input type="checkbox"/> DK/Refused

	E3. What was the outcome of your (first/next) pregnancy?	E4. How many weeks or months did this pregnancy last?	E5. In what month and year did this pregnancy end?	E6. Did you breast-feed this baby? If so, for how long?
c	1 <input type="checkbox"/> Single live birth 2 <input type="checkbox"/> Multiple birth, any living	_____ Months Or _____ Weeks	_____/_____ Month Year	1 <input type="checkbox"/> Yes E6i. How long? ↓ _____ Months
	3 <input type="checkbox"/> Multiple birth, none living 4 <input type="checkbox"/> Stillbirth 5 <input type="checkbox"/> Spontaneous miscarriage 6 <input type="checkbox"/> Induced abortion 7 <input type="checkbox"/> Tubal or ectopic pregnancy 8 <input type="checkbox"/> Other (specify): _____ _____ _____ _____	_____ Months Or _____ Weeks	_____/_____ Month Year	2 <input type="checkbox"/> No 9 <input type="checkbox"/> DK/Refused
d	1 <input type="checkbox"/> Single live birth 2 <input type="checkbox"/> Multiple birth, any living	_____ Months Or _____ Weeks	_____/_____ Month Year	1 <input type="checkbox"/> Yes E6j. How long? ↓ _____ Months
	3 <input type="checkbox"/> Multiple birth, none living 4 <input type="checkbox"/> Stillbirth 5 <input type="checkbox"/> Spontaneous miscarriage 6 <input type="checkbox"/> Induced abortion 7 <input type="checkbox"/> Tubal or ectopic pregnancy 8 <input type="checkbox"/> Other (specify): _____ _____ _____ _____	_____ Months Or _____ Weeks	_____/_____ Month Year	2 <input type="checkbox"/> No 9 <input type="checkbox"/> DK/Refused
e	1 <input type="checkbox"/> Single live birth 2 <input type="checkbox"/> Multiple birth, any living	_____ Months Or _____ Weeks	_____/_____ Month Year	1 <input type="checkbox"/> Yes E6k. How long? ↓ _____ Months
	3 <input type="checkbox"/> Multiple birth, none living 4 <input type="checkbox"/> Stillbirth 5 <input type="checkbox"/> Spontaneous miscarriage 6 <input type="checkbox"/> Induced abortion 7 <input type="checkbox"/> Tubal or ectopic pregnancy 8 <input type="checkbox"/> Other (specify): _____ _____ _____ _____	_____ Months Or _____ Weeks	_____/_____ Month Year	2 <input type="checkbox"/> No 9 <input type="checkbox"/> DK/Refused

	E3. What was the outcome of your (first/next) pregnancy?	E4. How many weeks or months did this pregnancy last?	E5. In what month and year did this pregnancy end?	E6. Did you breast-feed this baby? If so, for how long?
f	1 <input type="checkbox"/> Single live birth 2 <input type="checkbox"/> Multiple birth, any living	_____ Months Or _____ Weeks	_____/_____ Month Year	1 <input type="checkbox"/> Yes E6i. How long? ↓ _____ Months
	3 <input type="checkbox"/> Multiple birth, none living 4 <input type="checkbox"/> Stillbirth 5 <input type="checkbox"/> Spontaneous miscarriage 6 <input type="checkbox"/> Induced abortion 7 <input type="checkbox"/> Tubal or ectopic pregnancy 8 <input type="checkbox"/> Other (specify): _____ _____ _____ _____	_____ Months Or _____ Weeks	_____/_____ Month Year	2 <input type="checkbox"/> No 9 <input type="checkbox"/> DK/Refused
g	1 <input type="checkbox"/> Single live birth 2 <input type="checkbox"/> Multiple birth, any living	_____ Months Or _____ Weeks	_____/_____ Month Year	1 <input type="checkbox"/> Yes E6j. How long? ↓ _____ Months
	3 <input type="checkbox"/> Multiple birth, none living 4 <input type="checkbox"/> Stillbirth 5 <input type="checkbox"/> Spontaneous miscarriage 6 <input type="checkbox"/> Induced abortion 7 <input type="checkbox"/> Tubal or ectopic pregnancy 8 <input type="checkbox"/> Other (specify): _____ _____ _____ _____	_____ Months Or _____ Weeks	_____/_____ Month Year	2 <input type="checkbox"/> No 9 <input type="checkbox"/> DK/Refused
h	1 <input type="checkbox"/> Single live birth 2 <input type="checkbox"/> Multiple birth, any living	_____ Months Or _____ Weeks	_____/_____ Month Year	1 <input type="checkbox"/> Yes E6k. How long? ↓ _____ Months
	3 <input type="checkbox"/> Multiple birth, none living 4 <input type="checkbox"/> Stillbirth 5 <input type="checkbox"/> Spontaneous miscarriage 6 <input type="checkbox"/> Induced abortion 7 <input type="checkbox"/> Tubal or ectopic pregnancy 8 <input type="checkbox"/> Other (specify): _____ _____ _____ _____	_____ Months Or _____ Weeks	_____/_____ Month Year	2 <input type="checkbox"/> No 9 <input type="checkbox"/> DK/Refused

	E3. What was the outcome of your (first/next) pregnancy?	E4. How many weeks or months did this pregnancy last?	E5. In what month and year did this pregnancy end?	E6. Did you breast-feed this baby? If so, for how long?

i	1 <input type="checkbox"/> Single live birth 2 <input type="checkbox"/> Multiple birth, any living	_____ Months Or _____ Weeks	_____ / _____ Month Year	1 <input type="checkbox"/> Yes E6i. How long? ↓ _____ Months 2 <input type="checkbox"/> No 9 <input type="checkbox"/> DK/Refused
	3 <input type="checkbox"/> Multiple birth, none living 4 <input type="checkbox"/> Stillbirth 5 <input type="checkbox"/> Spontaneous miscarriage 6 <input type="checkbox"/> Induced abortion 7 <input type="checkbox"/> Tubal or ectopic pregnancy 8 <input type="checkbox"/> Other (specify): _____	_____ Months Or _____ Weeks	_____ / _____ Month Year	2 <input type="checkbox"/> No 9 <input type="checkbox"/> DK/Refused
j	1 <input type="checkbox"/> Single live birth 2 <input type="checkbox"/> Multiple birth, any living	_____ Months Or _____ Weeks	_____ / _____ Month Year	1 <input type="checkbox"/> Yes E6j. How long? ↓ _____ Months 2 <input type="checkbox"/> No 9 <input type="checkbox"/> DK/Refused
	3 <input type="checkbox"/> Multiple birth, none living 4 <input type="checkbox"/> Stillbirth 5 <input type="checkbox"/> Spontaneous miscarriage 6 <input type="checkbox"/> Induced abortion 7 <input type="checkbox"/> Tubal or ectopic pregnancy 8 <input type="checkbox"/> Other (specify): _____	_____ Months Or _____ Weeks	_____ / _____ Month Year	2 <input type="checkbox"/> No 9 <input type="checkbox"/> DK/Refused
k	1 <input type="checkbox"/> Single live birth 2 <input type="checkbox"/> Multiple birth, any living	_____ Months Or _____ Weeks	_____ / _____ Month Year	1 <input type="checkbox"/> Yes E6k. How long? ↓ _____ Months 2 <input type="checkbox"/> No 9 <input type="checkbox"/> DK/Refused
	3 <input type="checkbox"/> Multiple birth, none living 4 <input type="checkbox"/> Stillbirth 5 <input type="checkbox"/> Spontaneous miscarriage 6 <input type="checkbox"/> Induced abortion 7 <input type="checkbox"/> Tubal or ectopic pregnancy 8 <input type="checkbox"/> Other (specify): _____	_____ Months Or _____ Weeks	_____ / _____ Month Year	2 <input type="checkbox"/> No 9 <input type="checkbox"/> DK/Refused

E3. What was the outcome of your (first/next) pregnancy?	E4. How many weeks or months did this pregnancy last?	E5. In what month and year did this pregnancy end?	E6. Did you breast-feed this baby? If so, for how long?
--	---	--	---

I	1 <input type="checkbox"/> Single live birth 2 <input type="checkbox"/> Multiple birth, any living	_____ Months Or _____ Weeks	_____ / _____ Month Year	1 <input type="checkbox"/> Yes E6l. How long? ↓ _____ Months 2 <input type="checkbox"/> No 9 <input type="checkbox"/> DK/Refused
	3 <input type="checkbox"/> Multiple birth, none living 4 <input type="checkbox"/> Stillbirth 5 <input type="checkbox"/> Spontaneous miscarriage 6 <input type="checkbox"/> Induced abortion 7 <input type="checkbox"/> Tubal or ectopic pregnancy 8 <input type="checkbox"/> Other (specify): _____	_____ Months Or _____ Weeks	_____ / _____ Month Year	
m	1 <input type="checkbox"/> Single live birth 2 <input type="checkbox"/> Multiple birth, any living	_____ Months Or _____ Weeks	_____ / _____ Month Year	1 <input type="checkbox"/> Yes E6m. How long? ↓ _____ Months 2 <input type="checkbox"/> No 9 <input type="checkbox"/> DK/Refused
	3 <input type="checkbox"/> Multiple birth, none living 4 <input type="checkbox"/> Stillbirth 5 <input type="checkbox"/> Spontaneous miscarriage 6 <input type="checkbox"/> Induced abortion 7 <input type="checkbox"/> Tubal or ectopic pregnancy 8 <input type="checkbox"/> Other (specify): _____	_____ Months Or _____ Weeks	_____ / _____ Month Year	
n	1 <input type="checkbox"/> Single live birth 2 <input type="checkbox"/> Multiple birth, any living	_____ Months Or _____ Weeks	_____ / _____ Month Year	1 <input type="checkbox"/> Yes E6n. How long? ↓ _____ Months 2 <input type="checkbox"/> No 9 <input type="checkbox"/> DK/Refused
	3 <input type="checkbox"/> Multiple birth, none living 4 <input type="checkbox"/> Stillbirth 5 <input type="checkbox"/> Spontaneous miscarriage 6 <input type="checkbox"/> Induced abortion 7 <input type="checkbox"/> Tubal or ectopic pregnancy 8 <input type="checkbox"/> Other (specify): _____	_____ Months Or _____ Weeks	_____ / _____ Month Year	

	E7. During any of your pregnancies did a doctor ever tell you that you had:	E8. Which pregnancies were they?
a	Hypertension or high blood pressure? 1 <input type="checkbox"/> Yes _____→ 2 <input type="checkbox"/> No (E7b) 9 <input type="checkbox"/> DK/Refused (E7b)	a. _____ (Pregnancy letter) b. _____ (Pregnancy letter) c. _____ (Pregnancy letter) d. _____ (Pregnancy letter)
b	Toxemia or pre-eclampsia? This is when you have high blood pressure, swelling <u>and</u> protein in your urine. 1 <input type="checkbox"/> Yes _____→ 2 <input type="checkbox"/> No (E7c) 9 <input type="checkbox"/> DK/Refused (E7c)	a. _____ (Pregnancy letter) b. _____ (Pregnancy letter) c. _____ (Pregnancy letter) d. _____ (Pregnancy letter)
c	Diabetes or high blood sugar? 1 <input type="checkbox"/> Yes _____→ 2 <input type="checkbox"/> No (F1) 9 <input type="checkbox"/> DK/Refused (F1)	a. _____ (Pregnancy letter) b. _____ (Pregnancy letter) c. _____ (Pregnancy letter) d. _____ (Pregnancy letter)

F. ORAL CONTRACEPTIVES AND HORMONE REPLACEMENT THERAPY

Now I'd like to ask you about your use of hormones for birth control, menopause or other reasons.

F1. Before (RD) had you ever used pills, shots, patches or hormone implants for birth control or to regulate periods?

- 1 ☐ Yes
2 ☐ No (F5)
9 ☐ DK/Refused (F5)

F2. How old were you when you first started using pills, shots, patches or hormone implants for birth control or to regulate periods?

___ age

F3. How old were you when you last used pills, shots, patches or hormone implants for birth control or to regulate periods?

___ age

00 ☐ Still Taking

F4. Considering that you may have started and stopped several times, for how many months or years altogether did you use pills, shots, patches or implants for birth control or to regulate periods?

___ months OR ___ years

Now I am going to ask you questions about hormones that you may have taken for other reasons than birth control or to regulate periods. If you have had breast cancer, please do not include hormones that were taken for treatment of your breast cancer.

F5. Before (RD), had you ever used estrogen, progestins, or other female hormones for hormone replacement therapy during or after the change of life? This includes for menopausal symptoms, osteoporosis or heart disease.

- 1 ☐ Yes
2 ☐ No (G1)
9 ☐ DK/Refused (G1)

	F6. Do you recall the name of the hormone that you (first/next) used? <div>Show Card</div>	F7. What type of hormones did you use? <div>Show Card</div>	F8. At what age or in what year did you start taking (hormone in F6)?	F9. At what age or in what year did you stop taking (hormone in F6)?	F10. For how many months or years altogether did you take hormone in F6?
a	1 <input type="checkbox"/> Yes (specify): _____ (F8) _ _ _ 2 <input type="checkbox"/> No (F7)	1 <input type="checkbox"/> Estrogen only 2 <input type="checkbox"/> Progesterin only 3 <input type="checkbox"/> Both Estrogen and Progesterin 9 <input type="checkbox"/> DK/Refused	____ year OR ____ age 00 <input type="checkbox"/> still taking	____ year OR ____ age 00 <input type="checkbox"/> still taking	____ months OR ____ years
b	1 <input type="checkbox"/> Yes (specify): _____ (F8) _ _ _ 2 <input type="checkbox"/> No (F7)	1 <input type="checkbox"/> Estrogen only 2 <input type="checkbox"/> Progesterin only 3 <input type="checkbox"/> Both Estrogen and Progesterin 9 <input type="checkbox"/> DK/Refused	____ year OR ____ age 00 <input type="checkbox"/> still taking	____ year OR ____ age 00 <input type="checkbox"/> still taking	____ months OR ____ years
c	1 <input type="checkbox"/> Yes (specify): _____ (F8) _ _ _ 2 <input type="checkbox"/> No (F7)	1 <input type="checkbox"/> Estrogen only 2 <input type="checkbox"/> Progesterin only 3 <input type="checkbox"/> Both Estrogen and Progesterin 9 <input type="checkbox"/> DK/Refused	____ year OR ____ age 00 <input type="checkbox"/> still taking	____ year OR ____ age 00 <input type="checkbox"/> still taking	____ months OR ____ years

	F6. Do you recall the name of the hormone that you (first/next) used? <div>Show Card</div>	F7. What type of hormones did you use? <div>Show Card</div>	F8. At what age or in what year did you <u>start</u> taking (hormone in F6)?	F9. At what age or in what year did you <u>stop</u> taking (hormone in F6)?	F10. For how many months or years altogether did you take hormone in F6?
d	1 <input type="checkbox"/> Yes (specify): _____ (F8) 2 <input type="checkbox"/> No (F7)	1 <input type="checkbox"/> Estrogen only 2 <input type="checkbox"/> Progesterin only 3 <input type="checkbox"/> Both Estrogen and Progesterin 9 <input type="checkbox"/> DK/Refused	____ year OR ____ age 00 <input type="checkbox"/> still taking	____ year OR ____ age 00 <input type="checkbox"/> still taking	____ months OR ____ years
e	1 <input type="checkbox"/> Yes (specify): _____ (F8) 2 <input type="checkbox"/> No (F7)	1 <input type="checkbox"/> Estrogen only 2 <input type="checkbox"/> Progesterin only 3 <input type="checkbox"/> Both Estrogen and Progesterin 9 <input type="checkbox"/> DK/Refused	____ year OR ____ age	____ year OR ____ age 00 <input type="checkbox"/> still taking	____ months OR ____ years
f	1 <input type="checkbox"/> Yes (specify): _____ (F8) 2 <input type="checkbox"/> No (F7)	1 <input type="checkbox"/> Estrogen only 2 <input type="checkbox"/> Progesterin only 3 <input type="checkbox"/> Both Estrogen and Progesterin 9 <input type="checkbox"/> DK/Refused	____ year OR ____ age	____ year OR ____ age 00 <input type="checkbox"/> still taking	____ months OR ____ years

G. MAMMOGRAPHY SCREENING

A mammogram is an x-ray taken only of the breasts by a machine that presses the breast between two plastic plates. In the following questions, please tell me about your mammography history. For women with breast cancer: Please EXCLUDE any mammograms that were used to diagnose your recent breast cancer.

G1. Has a doctor ever recommended that you have a screening mammogram?

- 1 ☐ Yes
 2 ☐ No
 9 ☐ DK/Refused

G2. Before (RD), had you ever had a screening mammogram?

- 1 ☐ Yes
 2 ☐ No (G6)
 9 ☐ DK/Refused (G6)

G3. Before (RD) at what age or what year did you have your first screening mammogram?

____ OR ____
 Age Year

G4. How many screening mammograms had you had before (RD)?

____ number of mammograms (If participant only had 1 mammogram then skip to G6).

G5. Before (RD) at what age or what year was your last screening mammogram?

____ OR ____ / ____
 Age Month Year

G6. Before the (RD) did you examine your breasts for lumps?

- 1 ☐ Yes
- 2 ☐ No
- 9 ☐ DK/Refused

Show
Card

G6a. How often did you perform breast self-exams?

- ☐ Once a day
- 02 ☐ Once a week
- 03 ☐ Twice a month
- 04 ☐ Once a month
- ☐ Once every other month (6 times/year)
- ☐ Once every third month (4 times/year)
- 07 ☐ 2-3 times/year
- 08 ☐ Once a year
- 09 ☐ Less than once a year
- 99 ☐ DK/Refused

G7. Before the (RD) did your healthcare provider examine your breasts for lumps?

- 1 ☐ Yes
- 2 ☐ No (G8)
- 9 ☐ DK/Refused (G8)

Show
Card

G7a. Before your (RD) when was your last clinical breast exam?

- 1 ☐ Within the last year
- 2 ☐ Within the last year and a half
- 3 ☐ Within the last 2 years
- 4 ☐ Within the last 2-5 years
- 5 ☐ More than 5 years ago
- 9 ☐ DK/Refused

G8. Before (RD), had a doctor ever told you that you had benign breast disease, such as non-cancerous cyst or breast lump?

- 1 ☐ Yes
- 2 ☐ No
- 9 ☐ DK/Refused

FOR WOMEN WITHOUT BREAST CANCER (CONTROLS) GO TO G10.

FOR WOMEN WITH BREAST CANCER (CASES) ONLY:

G9. How was your breast cancer first found?

- 01 ☐ Routine self-exam
- 02 ☐ Accidental self discovery
- 03 ☐ Accidental discovery by a partner
- 04 ☐ Routine physical exam by doctor
- 05 ☐ Routine mammogram
- 06 ☐ Some other way (specify) _____
- 99 ☐ DK/Refused

□ □ □

FOR CONTROLS ONLY:

G10. If you were to discover a lump in your breast, what hospital would you go to for medical attention?

(specify name)

G11. In what borough or city and state is this hospital located?

(specify borough or city and state)

H. SMOKING HISTORY

Now, I would like to ask you some questions about cigarette smoking.

H1. Have you ever smoked at least one cigarette per day for one year?

- 1 ☐ Yes
2 ☐ No (I1)
9 ☐ DK/Refused (I1)

H2. How old were you when you first started smoking cigarettes on a regular basis?

_____ age started

H3. When you first started smoking regularly, how many cigarettes did you smoke per day? (One package contains 20 cigarettes.)

_____ number of cigarettes

99 ☐ DK/ Refused

H4. Were you a smoker on (RD)?

- 1 ☐ Yes (H6)
2 ☐ No (H5)
9 ☐ DK/ Refused (H5)

H5. At what age did you last stop smoking cigarettes?

_____ age stopped

99 ☐ DK/ Refused

H6. Thinking about when you first started smoking until you stopped, or the present, was there ever a period of one year or more in which you did not smoke cigarettes?

- 1 ☐ Yes
2 ☐ No (H8)
9 ☐ DK/ Refused (H8)

H7. For how many years from when you started until you stopped, or the present, did you not smoke cigarettes?

_____ years

99 ☐ DK/ Refused

H8. On average, during periods that you smoked, how many cigarettes (do/did) you usually smoke per day? (One package contains 20 cigarettes.)

_____ number of cigarettes

999 ☐ DK/ Refused

If participant had a FTP, ask H9. If not, go to I1.

H9. Did you smoke anytime before your first full-term pregnancy?

- 1 ☐ Yes
2 ☐ No (I1)
9 ☐ DK/ Refused (I1)

H10. Considering that you may have started and stopped several times, for how many months or years total did you smoke before your first full-term pregnancy?

___ months OR ___ years 99 ☐ DK/ Refused

H11. During this time before your first full-term pregnancy, on average how many cigarettes did you smoke per day?

___ number of cigarettes 999 ☐ DK/ Refused

I. HAIR PRODUCTS

The next set of questions ask about your use of different hair products including hair dye, relaxers and cholesterol-containing conditioning hair creams. For these questions, we are only interested in products that you used consistently for at least one year.

11. Have you ever regularly dyed your hair for at least one year with permanent hair dye? By regularly we mean more than TWO times per year.

- 1 ☐ Yes
 2 ☐ No (18)
 9 ☐ DK/ Refused (18)

Now we'd like to know some more specific information about your hair coloring patterns. If you used different types of dye or colors during different times in your life, please tell me about them separately, but remember to only include times that you colored your hair for at least one year.

	12. At what age did you (first/next) regularly start coloring your hair?	13. What <u>shade</u> of hair color did you use?	14. Did you use a home-kit or was it done in a salon?	15. At what age did you <u>last</u> dye your hair this color?	16. For how many months or years did you dye your hair this color?	17. On average, <u>how often</u> did you color your hair?	Show Card
a	____ age	1 <input type="checkbox"/> Light (blonde, light brown) 2 <input type="checkbox"/> Medium (medium brown, red) 3 <input type="checkbox"/> Dark (dark brown, black)	1 <input type="checkbox"/> Home-kit: (Brand name) _____ 2 <input type="checkbox"/> Salon 3 <input type="checkbox"/> Both 9 <input type="checkbox"/> DK/Refused	____ age	_____ (months) or _____ (years)	1 <input type="checkbox"/> 4-6 months 2 <input type="checkbox"/> 2-3 months 3 <input type="checkbox"/> 6-8 weeks 4 <input type="checkbox"/> 4-5 weeks 5 <input type="checkbox"/> More than every 4 weeks 9 <input type="checkbox"/> DK/Refused	
b	____ age	1 <input type="checkbox"/> Light (blonde, light brown) 2 <input type="checkbox"/> Medium (medium brown, red) 3 <input type="checkbox"/> Dark (dark brown, black)	1 <input type="checkbox"/> Home-kit: (Brand name) _____ 2 <input type="checkbox"/> Salon 3 <input type="checkbox"/> Both 9 <input type="checkbox"/> DK/Refused	____ age	_____ (months) or _____ (years)	1 <input type="checkbox"/> 4-6 months 2 <input type="checkbox"/> 2-3 months 3 <input type="checkbox"/> 6-8 weeks 4 <input type="checkbox"/> 4-5 weeks 5 <input type="checkbox"/> More than every 4 weeks 9 <input type="checkbox"/> DK/Refused	

	12. At what age did you (first/next) regularly start coloring your hair?	13. What shade of hair color did you use?	14. Did you use a home-kit or was it done in a salon?	15. At what age did you last dye your hair this color?	16. For how many months or years did you dye your hair this color?	17. On average, how often did you color your hair?
c	— age	1 <input type="checkbox"/> Light (blonde, light brown) 2 <input type="checkbox"/> Medium (medium brown, red) 3 <input type="checkbox"/> Dark (dark brown, black)	1 <input type="checkbox"/> Home-kit: (Brand name) <input type="text"/> 2 <input type="checkbox"/> Salon 3 <input type="checkbox"/> Both 9 <input type="checkbox"/> DK/Refused	— age	— (months) or — (years)	1 <input type="checkbox"/> 4-6 months 2 <input type="checkbox"/> 2-3 months 3 <input type="checkbox"/> 6-8 weeks 4 <input type="checkbox"/> 4-5 weeks 5 <input type="checkbox"/> More than every 4 weeks 9 <input type="checkbox"/> DK/Refused
d	— age	1 <input type="checkbox"/> Light (blonde, light brown) 2 <input type="checkbox"/> Medium (medium brown, red) 3 <input type="checkbox"/> Dark (dark brown, black)	1 <input type="checkbox"/> Home-kit: (Brand name) <input type="text"/> 2 <input type="checkbox"/> Salon 3 <input type="checkbox"/> Both 9 <input type="checkbox"/> DK/Refused	— age	— (months) or — (years)	1 <input type="checkbox"/> 4-6 months 2 <input type="checkbox"/> 2-3 months 3 <input type="checkbox"/> 6-8 weeks 4 <input type="checkbox"/> 4-5 weeks 5 <input type="checkbox"/> More than every 4 weeks 9 <input type="checkbox"/> DK/Refused

Show
Card

18. Have you ever chemically relaxed or straightened your hair for at least one year?

- 1 ☐ Yes
 2 ☐ No (I14)
 9 ☐ DK/ Refused (I14)

Now we'd like to know some more specific information about the different ages you might have chemically relaxed or straightened your hair.

	I9. When you were (age from 1 st column), did you ever relax your hair?	I10. Between these ages, for how many months or years in total did you relax your hair?	I11. Between these ages, on average, how often did you relax your hair? <div>Show Card</div>	I12. Did you use lye or no-lye relaxers?	I13. Did you use a home-kit or was it done in a salon?
a. 12 years old or younger	1 <input type="checkbox"/> Yes 2 <input type="checkbox"/> No (b) 9 <input type="checkbox"/> DK/Refused (b)	<u> </u> (Months) or <u> </u> (Years)	1 <input type="checkbox"/> 4-6 months 2 <input type="checkbox"/> 2-3 months 3 <input type="checkbox"/> 6-8 weeks 4 <input type="checkbox"/> 4-5 weeks 5 <input type="checkbox"/> More than every 4 weeks 9 <input type="checkbox"/> DK/Refused	1 <input type="checkbox"/> Lye 2 <input type="checkbox"/> No lye 3 <input type="checkbox"/> Both 9 <input type="checkbox"/> DK/Refused	1 <input type="checkbox"/> Home-kit 2 <input type="checkbox"/> Salon 3 <input type="checkbox"/> Both 9 <input type="checkbox"/> DK/Refused
b. Between 13 and 19 years old	1 <input type="checkbox"/> Yes 2 <input type="checkbox"/> No (c) 9 <input type="checkbox"/> DK/Refused (c)	<u> </u> (Months) or <u> </u> (Years)	1 <input type="checkbox"/> 4-6 months 2 <input type="checkbox"/> 2-3 months 3 <input type="checkbox"/> 6-8 weeks 4 <input type="checkbox"/> 4-5 weeks 5 <input type="checkbox"/> More than every 4 weeks 9 <input type="checkbox"/> DK/Refused	1 <input type="checkbox"/> Lye 2 <input type="checkbox"/> No lye 3 <input type="checkbox"/> Both 9 <input type="checkbox"/> DK/Refused	1 <input type="checkbox"/> Home-kit 2 <input type="checkbox"/> Salon 3 <input type="checkbox"/> Both 9 <input type="checkbox"/> DK/Refused
c. 20 years old up until now	1 <input type="checkbox"/> Yes 2 <input type="checkbox"/> No (I14) 9 <input type="checkbox"/> DK/Refused (I14)	<u> </u> (Months) or <u> </u> (Years)	1 <input type="checkbox"/> 4-6 months 2 <input type="checkbox"/> 2-3 months 3 <input type="checkbox"/> 6-8 weeks 4 <input type="checkbox"/> 4-5 weeks 5 <input type="checkbox"/> More than every 4 weeks 9 <input type="checkbox"/> DK/Refused	1 <input type="checkbox"/> Lye 2 <input type="checkbox"/> No lye 3 <input type="checkbox"/> Both 9 <input type="checkbox"/> DK/Refused	1 <input type="checkbox"/> Home-kit 2 <input type="checkbox"/> Salon 3 <input type="checkbox"/> Both 9 <input type="checkbox"/> DK/Refused

I14. Have you ever used deep conditioning hair creams that contain cholesterol or placenta for at least one year?

- 1 ☐ Yes
 2 ☐ No (J1)
 9 ☐ DK/ Refused (J1)

Now we'd like to know some more specific information about the different ages you might have used deep conditioning hair creams that contain cholesterol or placenta.

	I15. When you were (age from 1 st column), did you ever use cholesterol/placenta hair conditioner?	I16. Between these ages, for how many months or years did you use these products?	I17. During this age range, how often did you use these products?
a. 12 years old or younger	1 <input type="checkbox"/> Yes 2 <input type="checkbox"/> No (b) 9 <input type="checkbox"/> DK/Refused (b)	<u> </u> (Months) or <u> </u> (Years)	1 <input type="checkbox"/> Daily 2 <input type="checkbox"/> Several times/week 3 <input type="checkbox"/> Once/week 4 <input type="checkbox"/> Every 2 weeks 5 <input type="checkbox"/> Once/month 6 <input type="checkbox"/> 2-3 times a year 9 <input type="checkbox"/> DK/Refused
b. Between 13 and 19 years old	1 <input type="checkbox"/> Yes 2 <input type="checkbox"/> No (c) 9 <input type="checkbox"/> DK/Refused (c)	<u> </u> (Months) or <u> </u> (Years)	1 <input type="checkbox"/> Daily 2 <input type="checkbox"/> Several times/week 3 <input type="checkbox"/> Once/week 4 <input type="checkbox"/> Every 2 weeks 5 <input type="checkbox"/> Once/month 6 <input type="checkbox"/> 2-3 times a year 9 <input type="checkbox"/> DK/Refused
c. 20 years old old up until now.	1 <input type="checkbox"/> Yes 2 <input type="checkbox"/> No (J1) 9 <input type="checkbox"/> DK/Refused (J1)	<u> </u> (Months) or <u> </u> (Years)	1 <input type="checkbox"/> Daily 2 <input type="checkbox"/> Several times/week 3 <input type="checkbox"/> Once/week 4 <input type="checkbox"/> Every 2 weeks 5 <input type="checkbox"/> Once/month 6 <input type="checkbox"/> 2-3 times a year 9 <input type="checkbox"/> DK/Refused

Show
Card

J. LIVING ENVIRONMENT

For the next set of questions we would like to know about others who lived in your home when you grew up.

J1. Between birth and age 20, at what ages did you live with your (relative/person)?

a. BIOLOGICAL MOTHER

AGE	0	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20
Lived with																					

☐ Never lived with this person

☐ DK

b. BIOLOGICAL FATHER

AGE	0	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20
Lived with																					

☐ Never lived with this person

☐ DK

c. STEPMOTHER/Adoptive Mother (Or other mother figure)

AGE	0	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20
Lived with																					

☐ Never lived with this person

☐ DK

d. STEPFATHER/Adoptive Father (Or other father figure)

AGE	0	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20
Lived with																					

☐ Never lived with this person

☐ DK

e. ANY UNRELATED MALE >18 () ()

AGE	0	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20
Lived with																					

☐ Never lived with this person

☐ DK

f. ANY UNRELATED FEMALE >18 () ()

AGE	0	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20
Lived with																					

☐ Never lived with this person

☐ DK

K. PASSIVE SMOKING EXPOSURE

K1. During your life, have you ever lived with someone who smoked regularly inside your home? This could be parents or siblings when you grew up, or partners or roommates as an adult.

- 1 ☐ Yes
 2 ☐ No (L1)
 9 ☐ DK/Refused (L1)

K2. Beginning from the time you were born, please tell me about the number of people you lived with who smoked and at what ages you lived with them. Let's start with the first 10 years of your life. How many smokers did you live with from birth to age 10?

0-10 years

AGE	0	1	2	3	4	5	6	7	8	9	10
Passive Smoking											

99 ☐ DK/Refused

11-20 years

AGE	11	12	13	14	15	16	17	18	19	20
Passive Smoking										

99 ☐ DK/Refused

21-30 years

AGE	21	22	23	24	25	26	27	28	29	30
Passive Smoking										

99 ☐ DK/Refused

31-40 years

AGE	31	32	33	34	35	36	37	38	39	40
Passive Smoking										

99 ☐ DK/Refused

41-50 years

AGE	41	42	43	44	45	46	47	48	49	50
Passive Smoking										

99 ☐ DK/Refused

51-60 years

AGE	51	52	53	54	55	56	57	58	59	60
Passive Smoking										

99 ☐ DK/Refused

61-74 years

AGE	61	62	63	64	65	66	67	68	69	70	71	72	73	74
Passive Smoking														

99 ☐ DK/Refused

L. ALCOHOL CONSUMPTION

Now, we would like to know about what kinds of alcohol and how much you drank at different times in your life.

L1. Have you ever consumed alcoholic beverages, such as beer, wine or liquor at least once a week for 6 months or more?

- 1 ☐ Yes
 2 ☐ No (M1)
 9 ☐ DK/Refused (M1)

L2. When you were (age), did you drink alcoholic beverages at least once a week for 6 months or more?	L3. For how many years?	L4. How many drinks per day, week, month or year (did/do) you usually have when you were (age)?
a. Under 20 years of age 1 <input type="checkbox"/> Yes 2 <input type="checkbox"/> No (L2b)	_____ years	_____ drinks per 1 <input type="checkbox"/> Day 2 <input type="checkbox"/> Week 3 <input type="checkbox"/> Month 4 <input type="checkbox"/> Year
b. 20-29 years of age 1 <input type="checkbox"/> Yes 2 <input type="checkbox"/> No (L2c)	_____ years	_____ drinks per 1 <input type="checkbox"/> Day 2 <input type="checkbox"/> Week 3 <input type="checkbox"/> Month 4 <input type="checkbox"/> Year
c. 30-39 years of age 1 <input type="checkbox"/> Yes 2 <input type="checkbox"/> No (L2d) 3 <input type="checkbox"/> Not that old yet	_____ years	_____ drinks per 1 <input type="checkbox"/> Day 2 <input type="checkbox"/> Week 3 <input type="checkbox"/> Month 4 <input type="checkbox"/> Year
d. 40-49 years of age 1 <input type="checkbox"/> Yes 2 <input type="checkbox"/> No (L2e) 3 <input type="checkbox"/> Not that old yet	_____ years	_____ drinks per 1 <input type="checkbox"/> Day 2 <input type="checkbox"/> Week 3 <input type="checkbox"/> Month 4 <input type="checkbox"/> Year
e. 50-59 years of age 1 <input type="checkbox"/> Yes 2 <input type="checkbox"/> No (L2f) 3 <input type="checkbox"/> Not that old yet	_____ years	_____ drinks per 1 <input type="checkbox"/> Day 2 <input type="checkbox"/> Week 3 <input type="checkbox"/> Month 4 <input type="checkbox"/> Year
f. Age 60 or older 1 <input type="checkbox"/> Yes 2 <input type="checkbox"/> No (M1) 3 <input type="checkbox"/> Not that old yet	_____ years	_____ drinks per 1 <input type="checkbox"/> Day 2 <input type="checkbox"/> Week 3 <input type="checkbox"/> Month 4 <input type="checkbox"/> Year

M. DEVELOPMENTAL HISTORY

Now I am going to ask you a few questions about your height and weight.

M1. When you were (AGE), how did your height compare with other girls your age? Were you the shortest, much shorter, somewhat shorter, about the same, somewhat taller, much taller, or the tallest?

	A. SHORTEST	B. MUCH SHORTER	C. SOMEWHAT SHORTER	D. ABOUT THE SAME	E. SOMEWHAT TALLER	F. MUCH TALLER	G. TALLEST
a. 7 or 8 years old (2 nd or 3 rd grade)	1	2	3	4	5	6	7
b. AGE AT FIRST MENSTRUAL PERIOD ()	1	2	3	4	5	6	7
c. 15 or 16 years old (10 th or 11 th grade)	1	2	3	4	5	6	7

M2. When you were (AGE CATEGORY), how did your weight compare with other girls your age? Were you the thinnest, much thinner, somewhat thinner, about the same, somewhat heavier, much heavier, or the heaviest?

	A. THINNEST	B. MUCH THINNER	C. SOMEWHAT THINNER	D. ABOUT THE SAME	E. SOMEWHAT HEAVIER	F. MUCH HEAVIER	G. HEAVIEST
a. 7 or 8 years old (2 nd or 3 rd grade)	1	2	3	4	5	6	7
b. AGE AT FIRST MENSTRUAL PERIOD ()	1	2	3	4	5	6	7
c. 15 or 16 years old (10 th or 11 th grade)	1	2	3	4	5	6	7

M3. At age 20, how tall were you without shoes?

HT: _ _ _ _

1 ☐ FEET, INCHES

2 ☐ CENTIMETERS

9 ☐ DK/Refused

M4. One year prior to (RD), how tall were you?

HT: _ _ _ _

1 ☐ FEET, INCHES

2 ☐ CENTIMETERS

9 ☐ DK/Refused

M5. How much did you weigh when you were (AGE)? If you were pregnant or nursing at this age, how much did you weigh the year before the pregnancy?

a. 20 years old	WT: __ __ __	1 <input type="checkbox"/> Pounds 2 <input type="checkbox"/> Kilograms 9 <input type="checkbox"/> DK/Refused
b. 30 years old	WT: __ __ __	1 <input type="checkbox"/> Pounds 2 <input type="checkbox"/> Kilograms 9 <input type="checkbox"/> DK/Refused
c. 40 years old	WT: __ __ __	1 <input type="checkbox"/> Pounds 2 <input type="checkbox"/> Kilograms 9 <input type="checkbox"/> DK/Refused
d. 50 years old	WT: __ __ __	1 <input type="checkbox"/> Pounds 2 <input type="checkbox"/> Kilograms 9 <input type="checkbox"/> DK/Refused
e. 60 years old	WT: __ __ __	1 <input type="checkbox"/> Pounds 2 <input type="checkbox"/> Kilograms 9 <input type="checkbox"/> DK/Refused
f. 70 years old	WT: __ __ __	1 <input type="checkbox"/> Pounds 2 <input type="checkbox"/> Kilograms 9 <input type="checkbox"/> DK/Refused

M6. One year prior to (RD), how much did you weigh? If you were pregnant or nursing at this age, how much did you weigh the year before the pregnancy?

WEIGHT: ____

- 1 ☐ POUNDS
2 ☐ KILOGRAMS
9 ☐ DK/REFUSED

M7. Before (RD), when you gained weight, where on your body in general did you tend to gain it most easily? Do not include any times when you were pregnant or nursing.

CHECK ALL THAT APPLY.

- 01 ☐ NEVER GAIN WEIGHT
- 02 ☐ AROUND THE CHEST AND SHOULDERS
- 03 ☐ AROUND THE WAIST
- 04 ☐ AROUND THE STOMACH
- 05 ☐ AROUND THE HIPS
- 06 ☐ AROUND THE THIGHS
- 07 ☐ AROUND THE BUTTOCKS
- 08 ☐ EQUALLY ALL OVER
- 09 ☐ OTHER (SPECIFY) _____
- 99 ☐ DK/Refused

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N. LIFETIME PHYSICAL ACTIVITY

Now I will be asking you about your physical activity patterns over your lifetime.

N1. When you were (AGE), how physically active were you compared to other girls your age? Would you describe yourself as being a lot more, a little more, about the same, a little less, or a lot less physically active than others?

	A. A LOT LESS	B. A LITTLE LESS	C. ABOUT THE SAME	D. A LITTLE MORE	E. A LOT MORE
a. 7 or 8 years old (2 nd or 3 rd grade)	1	2	3	4	5
b. AGE AT FIRST MENSTRUAL PERIOD	1	2	3	4	5
c. age 15 or 16 years old (10 th or 11 th grade)	1	2	3	4	5

Now I will ask you specifically about your occupation or volunteer work activities. Please consider every job, paid or unpaid, which you held for **at least 17 hours a week for 6 months or longer**.

N2. Have you ever worked for at least 17 hours a week for 6 months or longer in a year? This would include full-time or part-time, paid or unpaid work, and also any periods of self-employment.

- 1 ☐ Yes
 2 ☐ No Go to O1

Now I am going to ask you some more detailed information about your jobs. Jobs should be reported separately if they required different physical effort. For example, changing from book keeping to construction work within the same company would be considered a two separate jobs.

	N6. When did you <u>stop</u> working in this job?	N7. For how many years did you work in this job?	N8. For how many months each year did you do this?	N9. On average, how many hours per week did you work at this job?
01	_ _ _ _ YEAR OR _ _ _ AGE 00 <input type="checkbox"/> still working	_ _ _ YEARS	_ _ _ MONTHS PER YEAR	_ _ _ HOURS PER WEEK
02	_ _ _ _ YEAR OR _ _ _ AGE 00 <input type="checkbox"/> still working	_ _ _ YEARS	_ _ _ MONTHS PER YEAR	_ _ _ HOURS PER WEEK
03	_ _ _ _ YEAR OR _ _ _ AGE 00 <input type="checkbox"/> still working	_ _ _ YEARS	_ _ _ MONTHS PER YEAR	_ _ _ HOURS PER WEEK

N3. What was the title of the (first/next) paid or unpaid job you held?	N4a. During a typical day at this job, which of the following would you consider your main activities? CHECK ALL THAT APPLY	N4b. If R. provides more than one response for N4a ASK: What percent of time did you (ACTIVITY)?	N5. At what age or in what year, did you <u>start</u> working in this job?
<div> <div></div> <div></div> <div></div> <div></div> <div></div> </div> <div>04</div>	01 <input type="checkbox"/> Sitting 02 <input type="checkbox"/> Standing 03 <input type="checkbox"/> Walking 04 <input type="checkbox"/> Lifting, carrying or pushing items less than 25 pounds (11 kilograms) 05 <input type="checkbox"/> Lifting, carrying or pushing items at least 25 pounds (11 kilograms) 06 <input type="checkbox"/> Some other activity (specify) _____	<div> <div></div> <div></div> <div></div> <div></div> <div></div> </div> <div>%</div>	<div> <div></div> <div></div> <div></div> <div></div> <div></div> </div> <div>YEAR</div> <div>OR</div> <div> <div></div> <div></div> <div></div> </div> <div>AGE</div>
<div> <div></div> <div></div> <div></div> <div></div> <div></div> </div> <div>05</div>	01 <input type="checkbox"/> Sitting 02 <input type="checkbox"/> Standing 03 <input type="checkbox"/> Walking 04 <input type="checkbox"/> Lifting, carrying or pushing items less than 25 pounds (11 kilograms) 05 <input type="checkbox"/> Lifting, carrying or pushing items at least 25 pounds (11 kilograms) 06 <input type="checkbox"/> Some other activity (specify) _____	<div> <div></div> <div></div> <div></div> <div></div> <div></div> </div> <div>%</div>	<div> <div></div> <div></div> <div></div> <div></div> <div></div> </div> <div>YEAR</div> <div>OR</div> <div> <div></div> <div></div> <div></div> </div> <div>AGE</div>
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	N6. When did you <u>stop</u> working in this job?	N7. For how many years did you work in this job?	N8. For how many months each year did you do this?	N9. On average, how many hours per week did you work at this job?
04	_ _ _ _ YEAR OR _ _ AGE 00 <input type="checkbox"/> still working	_ _ YEARS	_ _ MONTHS PER YEAR	_ _ HOURS PER WEEK
05	_ _ _ _ YEAR OR _ _ AGE 00 <input type="checkbox"/> still working	_ _ YEARS	_ _ MONTHS PER YEAR	_ _ HOURS PER WEEK
06	_ _ _ _ YEAR OR _ _ AGE 00 <input type="checkbox"/> still working	_ _ YEARS	_ _ MONTHS PER YEAR	_ _ HOURS PER WEEK

N3. What was the title of the (first/next) paid or unpaid job you held?	N4a. During a typical day at this job, which of the following would you consider your main activities? CHECK ALL THAT APPLY	N4b. If R. provides more than one response for N4a ASK: What percent of time did you (ACTIVITY)?	N5. At what age or in what year, did you <u>start</u> working in this job?
<div>07</div> <div>_____</div>	01 <input type="checkbox"/> Sitting 02 <input type="checkbox"/> Standing 03 <input type="checkbox"/> Walking 04 <input type="checkbox"/> Lifting, carrying or pushing items less than 25 pounds (11 kilograms) 05 <input type="checkbox"/> Lifting, carrying or pushing items at least 25 pounds (11 kilograms) 06 <input type="checkbox"/> Some other activity (specify) _____	<div>____ ____ ____ %</div> <div>____ ____ ____ %</div> <div>____ ____ ____ %</div> <div>____ ____ ____ %</div> <div>____ ____ ____ %</div> <div>____ ____ ____ %</div>	<div>____ ____ ____ OR ____ ____ </div> <div>YEAR AGE</div>
<div>08</div> <div>_____</div>	01 <input type="checkbox"/> Sitting 02 <input type="checkbox"/> Standing 03 <input type="checkbox"/> Walking 04 <input type="checkbox"/> Lifting, carrying or pushing items less than 25 pounds (11 kilograms) 05 <input type="checkbox"/> Lifting, carrying or pushing items at least 25 pounds (11 kilograms) 06 <input type="checkbox"/> Some other activity (specify) _____	<div>____ ____ ____ %</div> <div>____ ____ ____ %</div> <div>____ ____ ____ %</div> <div>____ ____ ____ %</div> <div>____ ____ ____ %</div> <div>____ ____ ____ %</div>	<div>____ ____ ____ OR ____ ____ </div> <div>YEAR AGE</div>
<div>09</div> <div>_____</div>	01 <input type="checkbox"/> Sitting 02 <input type="checkbox"/> Standing 03 <input type="checkbox"/> Walking 04 <input type="checkbox"/> Lifting, carrying or pushing items less than 25 pounds (11 kilograms) 05 <input type="checkbox"/> Lifting, carrying or pushing items at least 25 pounds (11 kilograms) 06 <input type="checkbox"/> Some other activity (specify) _____	<div>____ ____ ____ %</div> <div>____ ____ ____ %</div> <div>____ ____ ____ %</div> <div>____ ____ ____ %</div> <div>____ ____ ____ %</div> <div>____ ____ ____ %</div>	<div>____ ____ ____ OR ____ ____ </div> <div>YEAR AGE</div>

	N6. When did you <u>stop</u> working in this job?	N7. For how many years did you work in this job?	N8. For how many months each year did you do this?	N9. On average, how many hours per week did you work at this job?
07	<div> <div> _ _ _ _ </div> <div>YEAR</div> </div> <div>OR</div> <div> <div> _ _ </div> <div>AGE</div> </div> <div>00 <input type="checkbox"/> still working</div>	<div> <div> _ _ </div> <div>YEARS</div> </div>	<div> <div> _ _ </div> <div>MONTHS PER YEAR</div> </div>	<div> <div> _ _ </div> <div>HOURS PER WEEK</div> </div>
08	<div> <div> _ _ _ _ </div> <div>YEAR</div> </div> <div>OR</div> <div> <div> _ _ </div> <div>AGE</div> </div> <div>00 <input type="checkbox"/> still working</div>	<div> <div> _ _ </div> <div>YEARS</div> </div>	<div> <div> _ _ </div> <div>MONTHS PER YEAR</div> </div>	<div> <div> _ _ </div> <div>HOURS PER WEEK</div> </div>
09	<div> <div> _ _ _ _ </div> <div>YEAR</div> </div> <div>OR</div> <div> <div> _ _ </div> <div>AGE</div> </div> <div>00 <input type="checkbox"/> still working</div>	<div> <div> _ _ </div> <div>YEARS</div> </div>	<div> <div> _ _ </div> <div>MONTHS PER YEAR</div> </div>	<div> <div> _ _ </div> <div>HOURS PER WEEK</div> </div>

O. EXERCISE, SPORTS AND LEISURE TIME PHYSICAL ACTIVITY

*Now I would like to know all of your exercise, sports, or leisure time activities that you did during your lifetime starting with your childhood and continuing to your (REFERENCE YEAR). Please consider any activities that you have participated in for **at least one hour per week for three months or more in any year**. In addition to sports and exercise, we are also interested in knowing whether you participated in exercise such as walking or biking to work or school.*

O1. Have you ever participated in any physical activities (exercise/sports) on a regular basis – that is, for at least one hour per week for 3 months or more in any year?

1 ☐ Yes

2 ☐ No (O8)

Let's go through these beginning with the activity you participated in at the youngest age, including your school years.

Ask all of the questions (O2-O7) for one exercise episode before asking about next episode. Seasonal activities done continuously (e.g. track every spring for four years) can be listed once. When activities were discontinued and then begun again later, code each interval of an activity separately so that activity patterns at various ages can be evaluated.

Activity	O2. In what activity did you (first/next) participate on a regular basis?	O3. At what age did you start (ACTIVITY) regularly?	O4. At what age did you stop (ACTIVITY)?	O5. For how many years in total did you (ACTIVITY) regularly?	O6. For how many months each year did you do this?	O7. On average, about how many hours per week did you actually (ACTIVITY)?
a	<div> <div> <div></div> <div></div> <div></div> <div></div> <div></div> <div></div> <div></div> <div></div> </div> <div> <div></div> <div></div> <div></div> <div></div> <div></div> <div></div> <div></div> <div></div> </div> </div>	<div> <div></div> <div></div> <div></div> <div></div> <div></div> <div></div> <div></div> <div></div> </div> <div>AGE</div>	<div> <div></div> <div></div> <div></div> <div></div> <div></div> <div></div> <div></div> <div></div> </div> <div>YEAR</div> <div>OR</div> <div> <div></div> <div></div> <div></div> <div></div> <div></div> <div></div> <div></div> <div></div> </div> <div>AGE</div>	<div> <div></div> <div></div> <div></div> <div></div> <div></div> <div></div> <div></div> <div></div> </div> <div>YEARS</div>	<div> <div></div> <div></div> <div></div> <div></div> <div></div> <div></div> <div></div> <div></div> </div> <div>MONTHS PER YEAR</div>	<div> <div></div> <div></div> <div></div> <div></div> <div></div> <div></div> <div></div> <div></div> </div> <div>HOURS</div> <div>:</div> <div> <div></div> <div></div> <div></div> <div></div> <div></div> <div></div> <div></div> <div></div> </div> <div>MIN PER WEEK</div>
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Activity	O2. In what activity did you (first/next) participate on a regular basis?	O3. At what age did you start (ACTIVITY) regularly?	O4. At what age did you stop (ACTIVITY)?	O5. For how many years in total did you (ACTIVITY) regularly?	O6. For how many months each year did you do this?	O7. On average, about how many hours per week did you actually (ACTIVITY)?
g	____ ____ ____ ____ ____	____ ____ ____ AGE	____ ____ ____ ____ ____ YEAR OR ____ ____ ____ AGE 00□ still doing	____ ____ ____ YEARS	____ ____ ____ ____ ____ MONTHS PER YEAR	____ ____ ____ :____ ____ ____ HOURS MIN PER WEEK
h	____ ____ ____ ____ ____	____ ____ ____ AGE	____ ____ ____ ____ ____ YEAR OR ____ ____ ____ AGE 00□ still doing	____ ____ ____ YEARS	____ ____ ____ ____ ____ MONTHS PER YEAR	____ ____ ____ :____ ____ ____ HOURS MIN PER WEEK
i	____ ____ ____ ____ ____	____ ____ ____ AGE	____ ____ ____ ____ ____ YEAR OR ____ ____ ____ AGE 00□ still doing	____ ____ ____ YEARS	____ ____ ____ ____ ____ MONTHS PER YEAR	____ ____ ____ :____ ____ ____ HOURS MIN PER WEEK
j	____ ____ ____ ____ ____	____ ____ ____ AGE	____ ____ ____ ____ ____ YEAR OR ____ ____ ____ AGE 00□ still doing	____ ____ ____ YEARS	____ ____ ____ ____ ____ MONTHS PER YEAR	____ ____ ____ :____ ____ ____ HOURS MIN PER WEEK
k	____ ____ ____ ____ ____	____ ____ ____ AGE	____ ____ ____ ____ ____ YEAR OR ____ ____ ____ AGE 00□ still doing	____ ____ ____ YEARS	____ ____ ____ ____ ____ MONTHS PER YEAR	____ ____ ____ :____ ____ ____ HOURS MIN PER WEEK
l	____ ____ ____ ____ ____	____ ____ ____ AGE	____ ____ ____ ____ ____ YEAR OR ____ ____ ____ AGE 00□ still doing	____ ____ ____ YEARS	____ ____ ____ ____ ____ MONTHS PER YEAR	____ ____ ____ :____ ____ ____ HOURS MIN PER WEEK

O8. Now, I would like to ask about your activities at home. Please, **do not include** activities you may do at your home or other people's home **for pay**. During the 12 months before (REFERENCE DATE), how much time did you spend (ACTIVITY)?

- a. actively caring for a child or children **under 2 years of age** (includes activities such as feeding, dressing, bathing, playing, and carrying)

1 ☐ None or less than one hour a week
 2 ☐ 1-19 hours a week
 3 ☐ 20 or more hours a week
 9 ☐ DK/ Refused

Show
Card

- b. actively caring for a child or children **between 2 and 5 years of age**

1 ☐ None or less than one hour a week
 2 ☐ 1-19 hours a week
 3 ☐ 20 or more hours a week
 9 ☐ DK/ Refused

Show
Card

- c. actively caring for a disabled child or elderly person (only count time actually feeding, dressing, moving, etc.)

1 ☐ None or less than one hour a week
 2 ☐ 1-19 hours a week
 3 ☐ 20 or more hours a week
 9 ☐ DK/ Refused

Show
Card

- d. preparing meals or cleaning up from meals on **weekdays**

1 ☐ None or less than 30 minutes (1/2 hour) a day
 2 ☐ 30 to 59 minutes (less than 1 hour) a day
 3 ☐ 60 to 89 minutes (less than 1 1/2 hours) a day
 4 ☐ 90 to 119 minutes (less than 2 hours) a day
 5 ☐ 2 or more hours a day
 9 ☐ DK/ Refused

Show
Card

- e. preparing meals or cleaning up from meals on **weekends**

1 ☐ None or less than 30 minutes (1/2 hour) a day
 2 ☐ 30 to 59 minutes (less than 1 hour) a day
 3 ☐ 60 to 89 minutes (less than 1 1/2 hours) a day
 4 ☐ 90 to 119 minutes (less than 2 hours) a day
 5 ☐ 2 or more hours a day
 9 ☐ DK/ Refused

Show
Card

- f. doing major cleaning, such as shampooing carpets, waxing floors, or washing walls or windows

1 ☐ None or less than once a month
 2 ☐ Once a month
 3 ☐ 2-3 times a month
 4 ☐ Once a week
 5 ☐ More than once a week
 9 ☐ DK/ Refused

Show
Card

g. doing routine cleaning such as dusting, laundry, vacuuming, or changing linens

- 1 ☐ None or less than once a month
2 ☐ Once a month
3 ☐ 2-3 times a month
4 ☐ Once a week
5 ☐ More than once a week
9 ☐ DK/ Refused

SHOW
CARD

h. going grocery shopping and pushing a shopping cart or carrying a basket

- 1 ☐ None or less than once a month
2 ☐ Once a month
3 ☐ 2-3 times a month
4 ☐ Once a week
5 ☐ More than once a week
9 ☐ DK/ Refused

SHOW
CARD

i. doing gardening or yard work, such as mowing lawn or raking leaves

- 1 ☐ None or less than once a month
2 ☐ Once a month
3 ☐ 2-3 times a month
4 ☐ Once a week
5 ☐ More than once a week
9 ☐ DK/ Refused

SHOW
CARD

j. doing heavy outdoor work, such as chopping wood, tilling soil, shoveling snow, or baling hay

- 1 ☐ None or less than once a month
2 ☐ Once a month
3 ☐ 2-3 times a month
4 ☐ Once a week
5 ☐ More than once a week
9 ☐ DK/ Refused

SHOW
CARD

k. doing major home decoration or repair, such as plumbing, tiling, painting or building

- 1 ☐ None or less than once a month
2 ☐ Once a month
3 ☐ 2-3 times a month
4 ☐ Once a week
5 ☐ More than once a week
9 ☐ DK/ Refused

SHOW
CARD

P. LIFE EVENTS

In this section, we want to know any and all years in which you experienced these life events up until you were 20 years old. Please indicate any and all years you witnessed or experienced...

P1. You witnessed or experienced a life threatening natural disaster or war.

AGE	0	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20
Natural disaster																					

☐ Never witnessed or experienced

☐ DK

P2. You witnessed or experienced a life threatening accident.

AGE	0	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20
Accident																					

☐ Never witnessed or experienced

☐ DK

P3. You witnessed or experienced a life threatening physical illness happening to you, a family member, or close friend.

AGE	0	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20
Illness																					

☐ Never witnessed or experienced

☐ DK

P4. You witnessed or experienced the death of a close family member, or friend.

AGE	0	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20
Death																					

☐ Never witnessed or experienced

☐ DK

P5. You witnessed or experienced mental illness happening to you, a close family member, or friend.

AGE	0	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20
Mental Illness																					

☐ Never witnessed or experienced

☐ DK

P6. You witnessed or experienced a life threatening violent act, attack, or assault.

AGE	0	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20
Violent Act																					

☐ Never witnessed or experienced

☐ DK

P7. Your living parents began living apart, got separated, or got divorced.

AGE	0	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20
Parents Marital Status																					

☐ Never witnessed or experienced

☐ DK

P. LIFE EVENTS (cont'd)

P8. One or both of your parents lost their job, or was out of work.

AGE	0	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20
Parents work history																					

☐ Never experienced

☐ DK

P9. You moved to a new neighborhood.

AGE	0	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20
New place																					

☐ Never experienced

☐ DK

P10. You had to leave home, or lived somewhere else.

AGE	0	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20
Left Home																					

☐ Never experienced

☐ DK

P11. A close family member or friend had to spend time in jail or prison.

AGE	0	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20
Prison life																					

☐ Never experienced

☐ DK

P12. A close family member or friend attempted or committed suicide.

AGE	0	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20
Suicide																					

☐ Never witnessed or experienced

☐ DK

P13. You had a close physical relationship with a boyfriend.

AGE	0	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20
Opposite Sex																					

☐ Never experienced

☐ DK

P14. You experienced sexual abuse (unwanted physical contact)

AGE	0	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20
Sexual abuse																					

☐ Never experienced

☐ DK

Q. OTHER DEMOGRAPHIC QUESTIONS

Q1. What is your marital status in the year before (RD)?

- 1 ☐ Married
- 2 ☐ Living as married
- 3 ☐ Widowed
- 4 ☐ Separated
- 5 ☐ Divorced
- 6 ☐ Single, never married or never lived as married. (Go to Q4)
- 9 ☐ DK/Refused

Q2. What was the highest grade of school that your SPOUSE/ PARTNER completed in the year before (RD)?

- 1 ☐ Less than 8th grade
- 2 ☐ 8th to 11th grade
- 3 ☐ High school graduate or equivalent (GED)
- 4 ☐ Technical or vocational school
- 5 ☐ Some college
- 6 ☐ College graduate
- 7 ☐ Post-graduate degree
- 9 ☐ DK/Refused

Q3. What was the usual occupation that your spouse/partner had in the year before (RD)?

Name of Job

Q4. What type of health insurance did you have in the year before (RD) ? (Check all that apply.)

- 01 ☐ Medicaid
- 02 ☐ Medicare
- 03 ☐ Employer-provided insurance (like Oxford, Blue Cross/Blue Shield, HIP)
- 04 ☐ Pay for insurance out of pocket
- 05 ☐ I do not have health insurance
- 06 ☐ Other (specify): _____
- 99 ☐ DK/Refused

If R is under 65 years of age, ask Q5. Otherwise continue to Q6.

Q5. Did you have a residential telephone on (RD)?

- 1 ☐ Yes
- 2 ☐ No
- 9 ☐ DK/Refused

Q6. Including income provided by you, your spouse/partner, and any other person living in your household, which range of figures on this card comes closest to your total household income before taxes for the last calendar year?

- 1 ☐ Less than \$15,000
- 2 ☐ \$15,000-\$19,999
- 3 ☐ \$20,000-24,999
- 4 ☐ \$25,000-34,999
- 5 ☐ \$35,000-49,999
- 6 ☐ \$50,000-69,999
- 7 ☐ \$70,000-89,999
- 8 ☐ \$90,000 or more
- 9 ☐ DK / Refused

Show
Card

Q7. How many people, including yourself, were supported by this income during the last calendar year?

(Number of people)

Complete this section after you have thanked and left the participant

INTERVIEW QUALITY

1. Where was the interview conducted?

- ☐ 1 Respondent's Home
☐ 2 Hospital or MD Office
☐ 3 Nursing Home
☐ 4 MSSM
☐ 5 Somewhere else, specify _____ | | | |

2. Was the respondent's overall cooperation:

- ☐ 1 Very good
☐ 2 Good
☐ 3 Fair (3)
☐ 4 Poor (3)

3. The main reason for the unsatisfactory or questionable quality of information is because: (Check all that apply).

- ☐ 1 Did not know enough information regarding the topic
☐ 2 Did not want to be more specific
☐ 3 Did not understand or speak english well
☐ 4 Was bored or uninterested
☐ 5 Was upset or depressed
☐ 6 Had poor hearing or speech
☐ 7 Was confused by frequent interruptions
☐ 8 Was emotionally unstable (drunk etc)
☐ 9 Was physically ill
☐ 10 Did not comprehend content
☐ 11 Gave conflicting responses
☐ 12 Other (specify) _____ | | | |

4. Other interviewer comments.

- ☐ 1 No Comments
☐ 2 Comments Below

_____ | | | |

_____ | | | |

PROJECT 2

"Impact of culturally tailored counseling on psychobehavioral outcomes and BRCA decision making among women with breast cancer"

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Project 2: "Impact of culturally tailored counseling on psychobehavioral outcomes and BRCA decision making among women with breast cancer"

Principal Investigator: Dr. Heiddis Valdimarsdottir

INTRODUCTION:

Between 5-10% of all breast cancer cases are inherited and demonstrate clear patterns of dominant transmission. These syndromes of breast cancer susceptibility have been linked to mutations in at least two genes, BRCA1 and BRCA2. Individuals with mutations in BRCA1/2 have a 40% to 85% cumulative risk of developing breast cancer and a 5% to 60% cumulative risk of developing ovarian cancer. The decision to undergo genetic testing for breast cancer susceptibility is complex, as women have to evaluate the many potential benefits (e.g., increased surveillance if a woman is found to be a mutation carrier) and risks (e.g., increased distress if a woman is found to be a mutation carrier) associated with genetic testing. An important goal of genetic counseling is to improve knowledge and comprehension about these benefits and risks that are involved in genetic testing. However, research in genetic counseling has shown that many counselees have difficulty comprehending probability information. Some studies of genetic counseling have demonstrated gains in knowledge. However, in that research, as many as one-half of the counselees were no better informed after their counseling. Lerman et al. demonstrated increased knowledge of BRCA1/2 testing following genetic counseling; however, the average knowledge scores were only 65% at the one-month follow-up assessment, with African American women having the smallest increases in knowledge. These results may not be surprising as African American women have been found to have less prior knowledge and information about genetic testing than other women. Lerman et al. reported that education and counseling increased the probability that African American women banked a blood sample for BRCA testing, but this was not the case for White women. However, our research indicates that although African American women may be willing to provide blood samples for genetic testing, 20% of them may decline to receive their test results once they are available. This is significantly higher than the 2% refusal rate that we have observed for White women. These findings raise the possibility that African American women may experience decisional conflict with regard to testing even after they have undergone standard genetic counseling. One explanation for these findings may be that standard genetic counseling does not specifically address the unique concerns and attitudes that African American women have about genetic testing. As reviewed in detail in the body of the grant, there is evidence that culture-specific variables play an important role in BRCA-decision making. For example, Hughes et al. reported that compared to White women, a greater proportion of African American women endorsed the following items as risks of BRCA testing: a) death from cancer is inevitable, b) modern medicine is not trustworthy, c) testing would be too difficult to handle emotionally, and d) testing might have a significant effect on family members. Another potential barrier to genetic testing among African Americans may be mistrust of the medical community, as African American women have reported that suspicion

influences their medical decisions in general. Genetic counseling that addresses these unique concerns may be more effective in reducing distress associated with testing which, in turn, may increase the likelihood that the counseling will be effective in increasing knowledge about genetics. Increasing knowledge about genetics may not only increase the probability that women make an informed decision with regard to testing, but it may also affect their attitudes toward surveillance and preventive options as well as increase the likelihood that they will talk to their family members about their breast cancer risk.

The goal of the proposed research is therefore to develop and evaluate the impact of culturally tailored genetic counseling on patient decision making regarding BRCA testing and subsequent cognitive, emotional, and behavioral outcomes. Newly diagnosed African American breast cancer patients will be randomized to receive either Standard Genetic Counseling (SGC) or Culturally Tailored Genetic Counseling (CT-GC). As the CT-GC addresses culture specific benefits and barriers to breast cancer susceptibility testing, we hypothesize that women in the CT-GC group will: 1) be more likely to elect the option that is most consistent with their personal preference; 2) report greater decisional satisfaction and less decisional conflict; 3) report less distress which, in turn, will enhance retention of knowledge and information provided in the counseling session; 4) report stronger intentions to adhere to screening guidelines and to participate in prevention options; and 5) be more likely to disseminate information provided in the counseling to their first-degree relatives.

BODY:

As indicated in our Statement of Work, our goal was to start recruiting participants into the study in month seven of the grant. Therefore, during year three, we would have expected to continue to recruit and enroll participants into the study and to be collecting study data. However, we have not been able to accomplish that goal as we are still waiting to receive HSRRB approval from the Department of Defense. We therefore propose to modify the timeline of all subject related tasks to add 24 months. Of note, in the past two years, we have: 1) developed the culturally-tailored manual as well as the take home counseling manual. 2) trained our genetic counselors to conduct culturally-tailored counseling; 3) trained interviewers and research assistants to administer questionnaires during both telephone and in-person interviews; 4) developed study databases in which to store the research data once we are able to begin recruitment. We were able to pilot test, under a different protocol, the culturally-tailored counseling. The pilot tests indicate that the culturally-tailored counseling is well liked by the women and effective in helping them with their testing decisions. We have also continually responded to the HSRRB's requests for information or protocol alterations in a timely fashion.

Due to the slow start of the study, because of difficulties in receiving HSRRB approval from the Department of Defense, we are making plans to extend recruitment to involve women outside of Project 1. Towards that end we are contacting and explaining the

study to surgeons and oncologist at various hospitals as well as support groups. There is a great interest in the study and willingness to refer women to the study once HSRRB approval has been granted from the Department of Defense.

KEY RESEARCH ACCOMPLISHMENTS:

At this point in the research, with no approval by the HSRRB of the USAMRAA, no results are yet available.

REPORTABLE OUTCOMES:

We received a grant from the DOD that is designed to investigate the Emotional, Biological and Cognitive Impact of a Brief Expressive Writing Intervention for African American Women at Familial Breast Cancer Risk. Graduates of Project 3 will be recruited into this study.

CONCLUSIONS:

To date, we have developed and pilot tested the culturally tailored genetic counseling intervention and all questionnaires have been prepared, finalized the study protocol, and trained key research personnel. As we have not received HSRRB approval from the Department of Defense, we have been unable to recruit participants into the study.

REFERENCES:

None

APPENDIX:

Take home counseling material

PROJECT 2 APPENDIX

TAKE HOME COUNSELING MATERIAL

Major Risk Factors for Breast and Ovarian Cancer

All women have a chance of developing breast **cancer** or ovarian cancer at some point in their life. Breast cancer is a very common disease. In the United States, many women (over 190,000) are diagnosed with the disease every year. Ovarian cancer is not as common. About 25,000 women develop ovarian cancer in a year.

But what causes these diseases? It is not one single thing. Breast or ovarian cancer results from a combination of **genetic** and **environmental factors**. Genetics deals with what is passed down from one generation to another in families, like brown eyes. Environmental factors mean anything else that happens to a person that is not passed down in the family. Let's talk about environmental factors:

Environmental Factor #1: Age

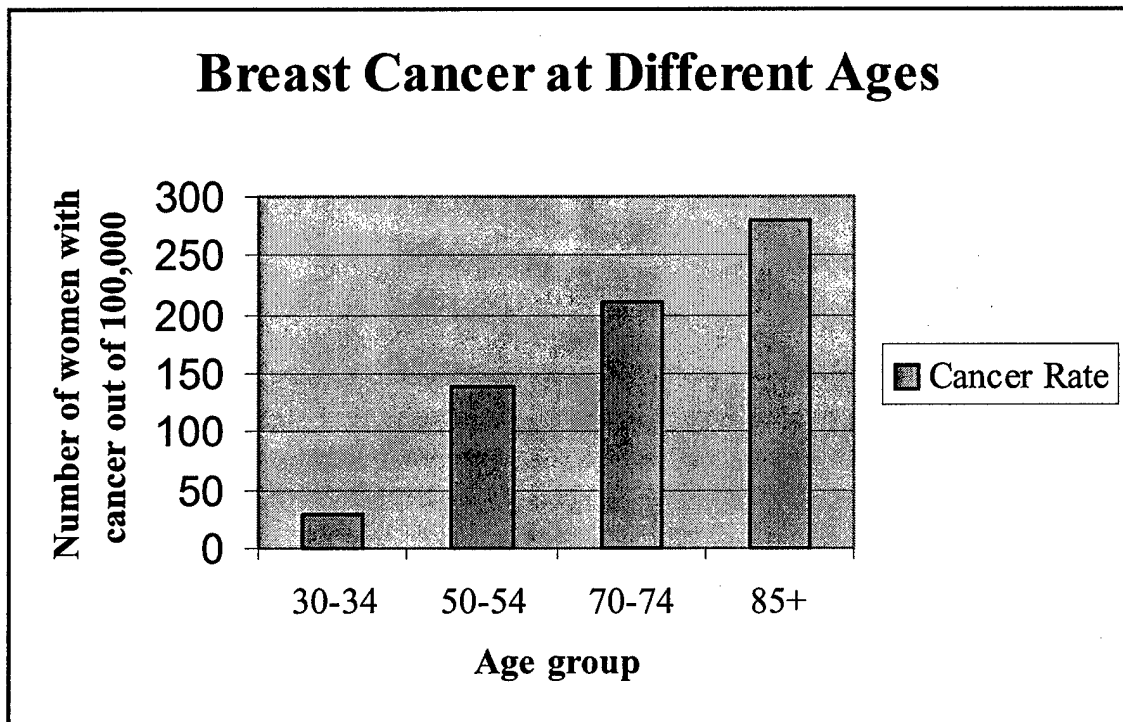
Age is a very important factor in whether a woman gets breast or ovarian cancer. The older a woman is, the higher the chances that she could develop cancer.

The next page shows a graph of how age is related to breast cancer.

Can you think of other environmental factors that affect your health?

What you eat

Look at this chart that shows how often women of different ages get breast cancer:



- If you walked down the street and asked 100,000 women ages 30-34 to step into one big room, less than 50 of them would have breast cancer.
- But, if you asked the same number of women who were 85 or older, almost 300 of them would have breast cancer. As you can see, there are more and more women with cancer as age gets higher.

Some women do get cancer at younger ages, such as in their 30s and 40s. This can be because of genetics. We will talk more about genetics later.

Environmental Factor #2: Family History of Cancer

A family history of cancer is another factor that can affect whether women develop breast or ovarian cancer.

If you have close relatives who have breast cancer, then you have a higher chance of getting breast cancer. A close relative could be a mother or sister. And if the relative's cancer was diagnosed at a young age, there is an even higher chance you could get cancer. This is also true if your relative had cancer in both breasts.

Environmental Factor #3: Personal History of Cancer

If you have breast cancer once, you have a higher chance of developing it again. You also have a slightly higher chance than other women of developing ovarian cancer.

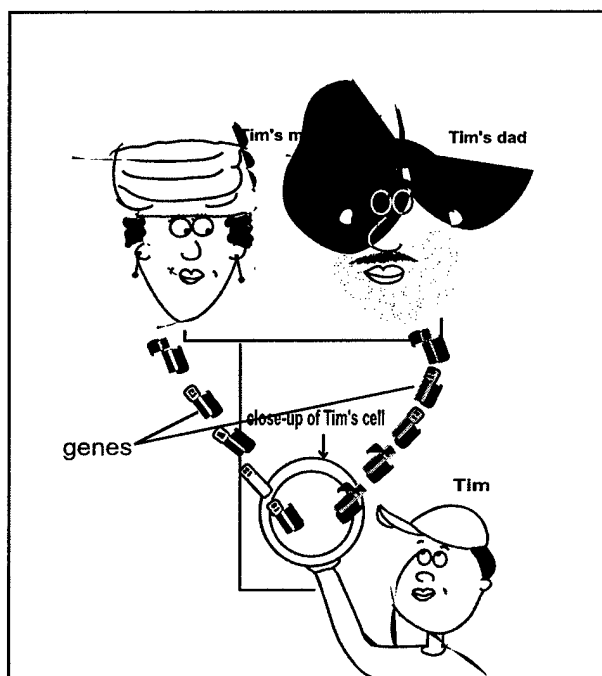
Sometimes women have a **mastectomy** (removing a breast) to treat their breast cancer. If that breast is removed, the woman could still get cancer in the other breast. Other times a lump is removed from the breast to treat breast cancer. This is called a **lumpectomy**. In this case, the woman could get cancer in the same breast again.

Genetics

In order to understand why some people have a higher chance of developing cancer, it is helpful to know about genetics.

First, let's look at **chromosomes**. As you probably know, the human body is made up of cells. Each cell has a **nucleus**, which is the control center. Chromosomes live in the nucleus. Chromosomes hardly get any elbow room – 46 of them are together in 1 nucleus!

Chromosomes come in pairs. The picture shows that one of each pair



is passed down from our mother and the other is passed down from our father.

Genes “live” on the chromosomes. Since chromosomes come in pairs, so do genes. Like the chromosomes, every gene has a partner. And genes are passed down the same way chromosomes are. Genes have a very important job. They are responsible for the instructions that control how the body

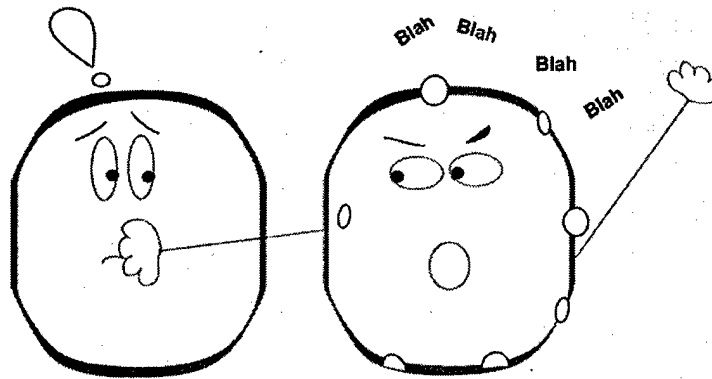
develops, grows, and works. Several genes are related to the chances of getting cancer.

When genes are working properly, our bodies develop properly and work smoothly. But sometimes genes have **mutations**. A mutation is a change in a gene that may make it work incorrectly. This can happen because the gene has too much or too little genetic material. Or, the genetic material may be rearranged.

When genes are not working correctly, the cell where those genes live can start to have trouble. For example, the cell could start growing in an “out of control” way and a cancer could develop. It turns out that not all gene mutations have a harmful effect. In fact, every person has many gene mutations that do not lead to changes you can notice. But sometimes, gene mutations do lead to the development of a disease.

Passing Down a Greater Chance of Cancer

Now you know what genes are and what they do. The way a tendency to develop breast cancer is passed down is called “**dominant inheritance**”. Let’s talk about what that means. Have you ever



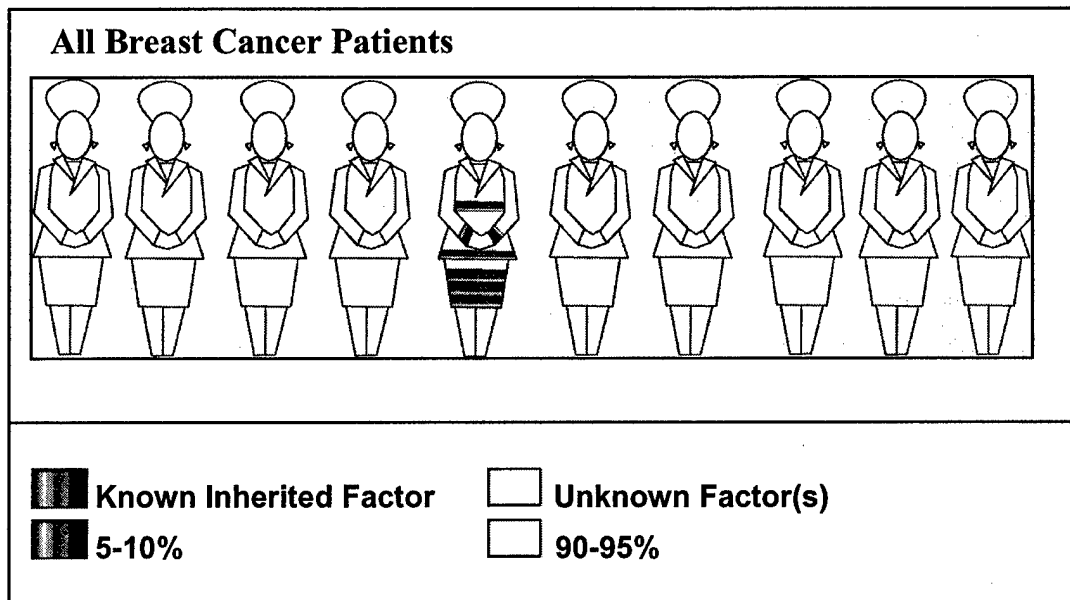
talked with someone who dominates, or controls, the whole conversation? You can hardly get a word in edgewise! Well, some genes dominate their partners too. Remember that genes come in pairs – like chromosomes; we get one gene from each parent. Each gene in a pair does the same job. With dominant inheritance, when only one gene in the pair has a mutation, the body may not work properly. It doesn’t matter if the other gene is just fine. Scientists have discovered two genes so far that deal with breast cancer. They are called **BRCA1** and **BRCA2**. When someone receives a non-working BRCA1 or BRCA2 gene from a parent, that non-working gene always dominates over its normal partner.

How do you get a BRCA mutation?

BRCA1 and BRCA2 are responsible for many breast and ovarian cancers that are passed down in families. Remember, not all cancer is **hereditary**, or passed down. In fact, scientists think that only 5 to 10% of all cases of breast cancer are hereditary.

Did you know?

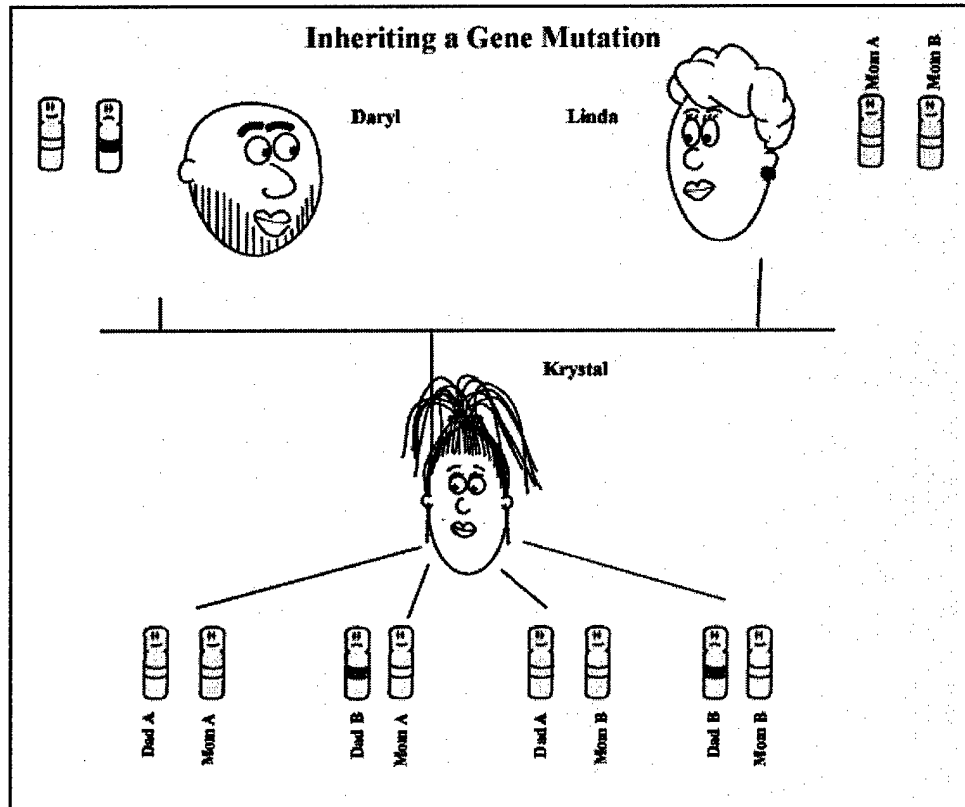
BRCA stands for
BReast Cancer



There is no way to tell when a child will receive the non-working gene. A child can receive the non-working gene from their mother or their father. The things listed below DO NOT give clues about who will receive the non-working gene:

1. Birth order
2. If the child is male or female
3. How much the child looks like the parent with the non-working gene
4. Whether the child was born before or after you were diagnosed with cancer

This family tree shows how Daryl and Linda can pass down a BRCA gene. As you can see, Daryl has a mutation in one of his BRCA genes:



Daryl and Linda will pass down one gene of each pair to every child they have. So, each child has a 50/50 (1 in 2) chance of having the gene passed down to them. Look at the possible combinations of genes Krystal could get from her parents. Every child Daryl and Linda had, boy or girl, will have one of these possible combinations.

You can have genetic testing to see if you have a mutation in your BRCA1 or BRCA2 genes. Later on you will read about the pros and cons of testing (in the section "Is genetic testing right for you?").

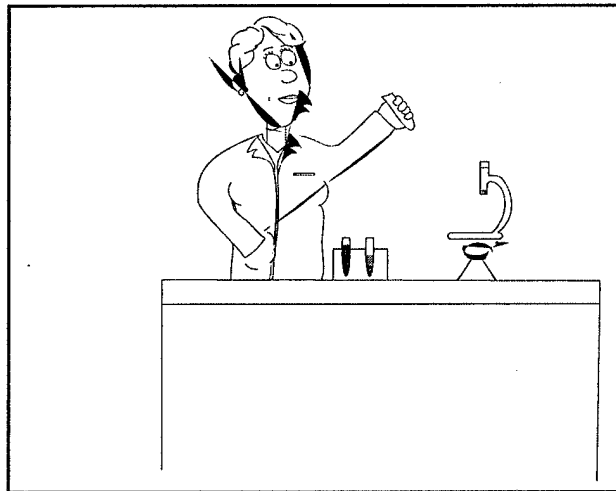
How Genetic Testing Works

Genetic tests are different from other medical tests. Usually, medical tests are **diagnostic**. That means they tell you if you have a certain condition. For example, a pregnancy test will tell you if you are pregnant, and an x-ray will tell you if you have a broken bone. But genetic tests for cancer do not work that way. They can't tell you if you have cancer or not. They also can't tell you if you will ever get cancer. They just tell you whether you have a **predisposition** to develop cancer. A predisposition means that you have a higher chance of developing the disease compared to most other people.

Let's use an example. Everyone has a chance of slipping and falling when they are walking around their house. But imagine that all of your floors have a sheet of ice over them. Because of the ice, you would have a higher chance of slipping in your house than would everyone else who has plain floors. So, you would have a predisposition to falling.

Now we'll talk about how genetic tests work. To do the test, a small blood sample is needed. Then, the genetic material in the blood cells is examined, to see if there are any mutations. The genetic material is called **DNA**.

One way scientists look for genetic mutations is called **sequencing**. This means that the "chemical alphabet" of a person's DNA is examined, and compared to DNA that is normal. This is a very hard thing to do. It's like looking for *one single spelling mistake* in a book that has 3,000 pages! That is why genetic testing takes a lot of time.



Genetic testing for BRCA1 and BRCA2

Let's talk about the results you get from genetic testing. Genetic tests need to be interpreted. Some genetic test results give more information than others.

Positive Test Results

A positive test result means that a genetic mutation was found. You may hear this result described as a "deleterious mutation". Having a mutation means you are more likely to develop cancer.

What does a positive result mean for my family?

Once a mutation in the BRCA1 or BRCA2 gene is found in one family member, it is easier to test other family members. For example, if "Dana" gets a positive result, then other family members would only be tested for the particular mutation that Dana has. It would not be necessary to look for every single possible change. In the case of the spelling example, this would be like finding the one spelling mistake in a 3,000-page book. Now for everyone else in the family who wants to be tested, we know exactly where to look. We know the page, sentence and word where the spelling mistake is. That is why it is quicker and easier to test other family members once a mutation has been found in a family.

Negative Test Results

A negative result means that no mutation was found. If "Tina" gets back a negative test, AND she already knows that someone else in her family has the same mutation, then Tina can be sure she doesn't have the mutation. So, her chances of getting cancer are like everyone else's. She has a similar chance of getting cancer as anyone in the **general population**. And, she cannot pass the mutation on to their children, because she doesn't have it.

There are also “unclear” negative test results. This kind of test result means the person did not show a genetic mutation in BRCA1 or BRCA2 – but, it is not possible to be 100% sure there are no changes there. Let’s use the example of looking for a spelling mistake to understand why.

Reasons why the test could have a negative result:

1. It could be that the methods we can use are not sensitive enough to find certain mutations in the BRCA1 or BRCA2 gene. For example, the change may be in a part of the gene that is hard to examine. In the spelling example, let’s say the only way we are able to look for mistakes is to just move our eyes over the page. Maybe that would work well in chapters with lots of pictures and not too many words. But in a chapter that has 500 words per page, maybe a magnifying glass would work better. Since we don’t have a magnifying glass, the test comes back negative – no spelling mistakes.

What happens if you get an unclear negative result?

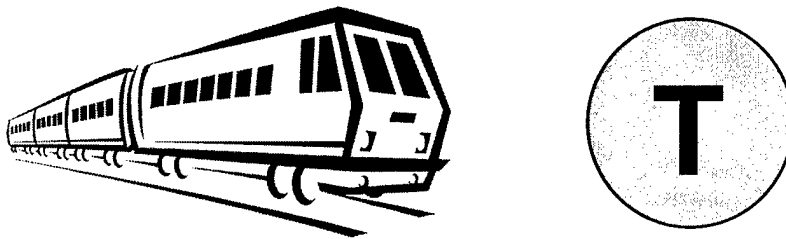
1. You could possibly get more genetic testing if more genes are discovered.
2. Family members may not be tested after you get your result. Why? Because if the test doesn’t show that you have a non-working gene, you can’t pass along something you don’t have.

2. It could be that there is a change present, but it is in a different gene, one that we can’t test for now. Scientists know that there are other genes related to cancer. But these genes are rare or not even discovered yet. In the spelling example, this would mean that we are looking for spelling mistakes in one book, because we know that book is related to cancer. If we don’t find any, the test comes back negative. But what if there is a second book that is also related to cancer? If we never even look for mistakes in the second book, we can’t be completely sure that there are no important changes.

Variants of Uncertain Significance

In some cases, a mutation may be found, but it is of unclear clinical significance. Basically that means there *is* a slight change in the gene, but scientists have not found that it is *definitely* related to higher chances of getting cancer.

Let's use an example to understand this. Let's say you have an appointment on Main Street, and you have to arrive on time. To get there you take the T train, which always goes express.



You know that if the T train goes express to Main Street, you will make it to your appointment on time. But imagine 3 different things that could happen to the train. In each situation, you are not sure if you will arrive on time. If this were a genetic test, these changes would be of “unclear significance”. Let's compare the train examples to genetic test results:

1. The train is delayed:
The conductor announces, “We hope to be moving shortly”.

What does that mean? Are you only going to be delayed a few minutes? Or is the train going to be stuck for half an hour? This result means, “there is a change that could mean something, but we're not sure”. In genetic testing, this would get the label **variant of unknown significance**.

2. The train goes slower:
The conductor announces, “The T train will be running local to Main Street.”

You can’t say for sure what time you will arrive, but you will probably make it to your appointment on time. So this result means, “this change probably doesn’t mean anything.” In genetic testing, this would get the label **variant of unknown significance, favor polymorphism**.

3. The train changes its route:
The conductor announces, “The T train will be skipping the Main Street stop. Passengers must ride to Central Street and go backwards.”

Here, the conductor has said that the train won’t be stopping at Main Street at all! You feel pretty sure that you are going to be late for your appointment now. So, this result means, “there is a change here, and most likely it means something—we doubt that it means nothing.” In genetic testing, this would get the label **variant of unknown significance, favor deleterious**.

Now you have an idea about the kinds of results that are of uncertain significance. Some results suggest that the changes in the gene could really mean something about your cancer risk, and others seem unlikely to have anything to do with that.

What does a variant result mean for my family?

If a person is found to have a variant genetic test result, it may be possible to test other family members to find out more about what the variant result really means.

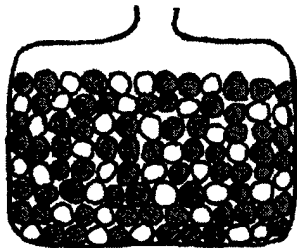
What does it mean if I have a BRCA mutation?

Both women and men with a BRCA mutation have a greater chance to get cancer. Let's talk about a person's chance to develop cancer if they have a BRCA1 or BRCA2 mutation. This chance to develop cancer varies from person to person. It also varies from family to family. Because of this, the numbers we are going to talk about are not exact. Below you can read about the lifetime chance that people with a BRCA mutation have to develop cancer.

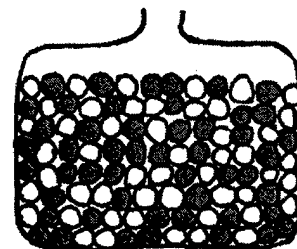
Breast Cancer Risks

A woman with a BRCA mutation has a higher chance of developing breast and ovarian cancer at a younger age. In general, she has a 55% to 85% chance to develop breast cancer over her lifetime. But this only applies to women who have never had a diagnosis of breast cancer. For a woman who has already had breast cancer, the numbers are different.

Below are pictures of jars filled with beads. Each jar contains 100 beads. The number of black beads in a jar represents a person's chance of getting cancer. These first two pictures are about a woman with a BRCA mutation who already had breast cancer. The pictures show the chances of her developing breast cancer again. Her chances are higher than for women in the general population. The pictures show the chances for both BRCA1 *and* BRCA2. In the picture on the left, 65 of the 100 beads in the jar are black. This means that a woman with a BRCA1 mutation has a 65 out of 100, or 65%, chance to get breast cancer in her other breast.



Here we see that for a woman with a BRCA1 mutation, her chance to get breast cancer (in her other breast) is up to 65%.

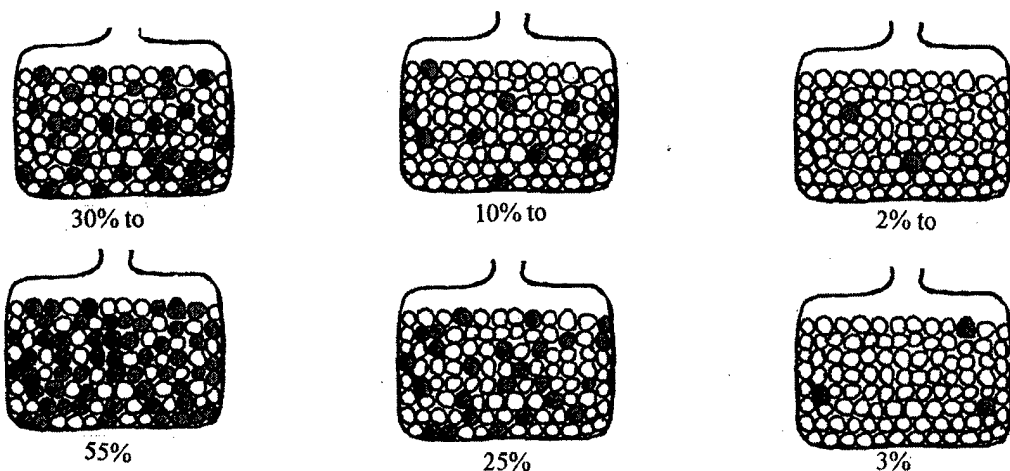


With a BRCA2 mutation, this chance is up to 50%.

A woman with a BRCA mutation who has already had breast cancer also has a greater chance of getting breast cancer again in the same breast. A woman with a BRCA mutation who has had ovarian cancer also has a greater chance to get breast cancer.

Ovarian Cancer Risks

In general, if a woman has a BRCA₁ mutation, she has a 15% to 60% chance to develop ovarian cancer over her lifetime. For a woman with a BRCA₂ mutation, she has a 15%-25% chance to develop ovarian cancer over her lifetime. But this only applies to women who have never had a diagnosis of breast cancer. For a woman who has already had breast cancer, the numbers are different. The pictures of beads in jars below show the chance to develop ovarian cancer for a woman with a BRCA mutation who has already had breast cancer:



For a woman with a BRCA₁ mutation who has already had breast cancer, her chance to get ovarian cancer is between 30% and 55%.

With a BRCA₂ mutation, this chance is between 10% and 25%.

This is compared to the general population risk of 2% to 3%.

Cancer Risks for Men

A man with a BRCA mutation has a greater chance to get prostate cancer. He also has an increased risk to get male breast cancer.

Colon Cancer Risks

Scientists are not sure if people with BRCA mutations have a greater chance to get colon cancer. Some studies have shown that there is a greater chance, while other studies have not.

Risks for Other Cancers

Men and women who have a BRCA₂ mutation have a greater chance to get other cancers. The chance to get these cancers is less than 10%, much lower than the chances to get breast, ovarian, or prostate cancer. Women with a BRCA₁ mutation may have a greater chance to get uterine and cervical cancer. Men and women with a BRCA₂ mutation may have a greater chance to get cancer of the pancreas, gallbladder, bile duct, stomach, and skin (melanoma).

Next we will talk about what a person with a BRCA mutation can do to manage their cancer risks.

What Can I Do if I Have a BRCA Mutation?

If you are found to have a BRCA mutation, or if you are not but you have a very strong family history of cancer...***Keep a watchful eye on developing cancer and protect your health!***

Breast and ovarian cancer **screening** are ways to possibly pick up cancer at an early stage. If you have a BRCA1 or BRCA2 mutation, there are also ways to prevent breast or ovarian cancer or at least lower your chances of developing these cancers.

If someone has a **BRCA** mutation, or if they have a very strong family history of cancer, they should follow these screening guidelines:

SCREENING FOR FEMALE BREAST CANCER:

- **Breast self-exams** every month.
- **Clinical breast examinations** (when a health care professional examines your breasts) 2-4 times a year, starting around age 25-35.
- **Mammography** (an x-ray of the breasts) once a year, starting around age 25-35.
- Sometimes **ultrasound** or **MRI** are also used to look for changes in breast tissue. These are other ways to make a picture of the breast tissue.

SCREENING FOR OVARIAN CANCER:

- **Pelvic exam** twice a year.
- **Vaginal ultrasound** twice a year, starting around age 25-35.
- **CA-125 blood test** twice a year, starting around age 25-35. This test looks for special markers in the blood that may tell if a woman has ovarian cancer.

Did you know?

These **screening** tests for ovarian cancer are currently the best tests available. But, they have not been proven to find ovarian cancer in its early stages.

SCREENING FOR COLON CANCER:

- **Fecal occult blood test** (a test to see if there is any blood in your stool) and **digital rectal exam** (done by your doctor) once per year, beginning by age 50, AND
- **Sigmoidoscopy** (a test that lets your health care professional look into the lower part of your colon) every 3-5 years, beginning by age 50.

OR

- **Colonoscopy** (a test that lets your health care professional look at your entire colon) every 5-10 years, beginning by age 50.

Did you know?

ALL men and women should start screening for colon cancer at age 50. If you have a BRCA mutation or you are at increased risk for inherited breast and/or ovarian cancer, you may have an increased risk to develop colon cancer. Therefore, it may be recommended that you start this screening before age 50. It may also be recommended that you have more frequent screening.

SCREENING FOR SKIN CANCER:

- Check your skin regularly for growths, sores that do not heal, changes in the size, shape or color of any moles, or any other changes in the skin. Report any changes to your health care professional right away.
- Have exams of your skin during regular checkups with your health care professional.
- Men and women who have a BRCA2 mutation should have an annual skin examination with a dermatologist.

What are other ways to protect myself from skin cancer?

- Do not stay in the sun for long periods of time.
- Use sunscreen for added protection.

SCREENING FOR PROSTATE CANCER (for male relatives):

- **PSA blood test** once a year, starting at age 40-50. This test looks for special markers in the blood that may tell if a man has prostate cancer.
- **Digital rectal exam** (done by your health care provider) once a year, starting at age 50.

Male breast cancer

Right now, there are no set screening recommendations for men who have a greater chance to develop breast cancer. But, it is important that these men report any changes in their breast tissue to their health care professional.

Preventing Breast and Ovarian Cancer

Let's discuss some ways to prevent breast or ovarian cancer, or at least lower your chances of developing these cancers. We will talk about **preventive surgery** and **chemoprevention**.

Preventive Surgery for Breast Cancer

Women who have a BRCA1 or BRCA2 mutation have a greater chance of getting breast cancer. Some of these women think about having a healthy breast removed in order to try to prevent breast cancer. This is known as **prophylactic mastectomy**. In this surgery, the entire breast is removed, including the nipple, but a small amount of breast tissue remains after this surgery. For that reason, there is still a small chance of developing breast cancer after having prophylactic mastectomy. Even if you have already had a mastectomy because of breast cancer, this surgery performed on the other breast can reduce the chance of a new breast cancer in that breast.

Preventive Surgery for Ovarian Cancer

Women who have a BRCA1 or BRCA2 mutation also have a greater chance of getting ovarian cancer. Some of these women may think about having their ovaries removed in order to prevent ovarian cancer. This surgery is known as a **prophylactic oophorectomy**. This surgery reduces the chance of developing ovarian cancer by over 90%. But, even after the surgery, there is still a small chance of developing an ovarian-like cancer.

Women may be more interested in this surgery if they have decided not to have children or have finished having children. Younger women who have this surgery will go through early **menopause**. Menopause is the change of life when your menstrual period ends.

How do I decide about preventive surgery?

If you have a BRCA mutation, there is no right or wrong decision about having preventive surgery. There are many things to think about before having surgery, including:

- How comfortable you are using breast and ovarian screening tests (like a mammogram or ultrasound)
- How comfortable you are with how much preventive surgery would lower your chances of developing breast and ovarian cancer
- How surgery would affect you emotionally
- Other medical conditions you may have that might affect surgery
- The financial costs involved in preventive surgery

Before making a decision, all of these issues should be discussed with your doctors. You may also want to discuss these issues with your family.

Chemoprevention

Chemoprevention means medication that can reduce cancer risk. There are different medications in this group. One common one is called **tamoxifen**. This medication affects hormones. Tamoxifen is often used by some women who have already had breast cancer. This is because tamoxifen can prevent the cancer from spreading. It also reduces the chance of getting a new breast cancer. Your doctor can tell you if tamoxifen is right for you.

For women who have a BRCA mutation, scientists are not yet sure whether tamoxifen reduces the chances of getting breast cancer or getting breast cancer again.

Remember, even if you decide to use chemoprevention, you must still get breast and ovarian cancer screening as described on pages 16-18.

Is Genetic Testing Right For You?

There are possible benefits (“pros”) to having genetic testing. There are also possible risks (“cons”). Everyone needs to think carefully about the pros and the cons in order to make their own decision about being tested.

PROS

Genetic testing can help you learn if you have a BRCA1 or BRCA2 mutation. Some people decide to have genetic testing because:

- It can give you more knowledge and information about your chance for getting a second, new cancer.
- It can help you make better healthcare decisions, especially about cancer screening tests (like how often to have them) and preventive surgery.
- It can provide important information for your family members, especially your children, sisters and brothers. For example, if you learn you have a BRCA1 or BRCA2 mutation, this may help your family members decide whether they want to be tested, too, since these mutations run in families.
- It can help you emotionally. If you learn that you have a BRCA1 or BRCA2 mutation, you may have more peace of mind because you are more certain about your chances of getting cancer. If you learn that you do not have a mutation, you may be relieved.
- It can give you a chance to help scientists understand more about inherited cancer and add to research.

CONS

Some people decide not to participate in genetic testing because:

- It is sometimes hard to make sense of test results (go back to pages 10-12 for more information).
- Genetic testing can be hard emotionally. People who learn that they have a BRCA1 or BRCA2 mutation may feel sad, angry or worried.
- Learning test results may put a strain on family relationships because people react differently to genetic testing. Family members may feel guilty about test results. For example, a person may feel badly if she learns that she does not have the mutation but her sister does. Sometimes, psychological counseling and support may be helpful.
- Genetic counselors do as much as possible to keep your genetic results private. But, if other members of your family decide to be tested, they may learn or figure out your test results based on your cancer history and position in the family tree.
- Some people worry that genetic test results can lead to discrimination or unfair treatment by employers or companies that provide health, life, or disability insurance.

Protection from Genetic Discrimination

The Health Insurance Portability and Accountability Act (HIPAA) says that genetic information is protected medical information. For example, what if someone needs to change insurance? HIPAA does not allow group health providers to deny health care to people who have a genetic

Am I protected from genetic discrimination?

There are laws that help protect people who undergo genetic testing from discrimination or unfair treatment.

mutation in BRCA1 or BRCA2. But, the HIPAA rules **do not apply** to people who are covered by private insurance. It also does not apply to disability and life insurance.

The Americans with Disabilities Act protects employees from genetic discrimination through the U.S. Equal Employment Opportunity Commission. But, these guidelines are not clear when it comes to genetic test results. Therefore, it may be hard to prove that an employer has acted against these guidelines.

An executive order signed by President Clinton in February 2000 makes it illegal for departments and agencies in the federal government to use genetic information in their hiring or promotion decisions. This is a good start but it does not apply to employees who do not work for the federal government.

Different states may also provide protection against genetic discrimination.

Although these laws do not protect everyone completely, they are important steps in protecting people who decide to have genetic testing.

Summary

This educational packet provides a lot of information about hereditary breast and ovarian cancer and genetic testing. Deciding whether to have genetic testing is a personal decision that must be carefully considered. There are no right or wrong answers. You may want to ask yourself if the information you could gain from genetic testing would be useful to you. What would you do with this information? Would this information change any of your current health care practices? You may also want to talk about the information provided in the packet with your health care providers, family, and friends. We hope that this information provided in this packet will help you to make this decision.

Glossary

BRCA1 and BRCA2 – two genes that scientists have discovered that deal with inherited breast and ovarian cancer. BRCA stands for BReast CAncer.

Breast Self-Exam – when a person examines their own breasts, using their hands to check the breasts for any abnormal signs.

CA-125 Blood test – a test that looks for special markers in the blood that may tell if a woman has ovarian cancer.

Cancer – a tumor that is able to grow uncontrollably.

Chemoprevention – (kee-moe-pruh-ven-shun) - the use of chemicals in the form of medicine to prevent the growth of cancer.

Chromosomes -- (kro-mo-zomes) – structures found in the nucleus that contain genes. Chromosomes come in pairs. A person gets one of each pair from their mother, and the other of each pair from their father.

Clinical Breast Exam – an exam in which a health care provider uses their hands to check the breasts for any abnormal signs.

Colonoscopy (koh-loh-nah-ska-pee) – an examination of the colon (large intestine) through a flexible, lighted instrument called a colonoscope.

Diagnostic test – a test that can identify a disease by looking for signs or symptoms of that disease.

Digital Rectal Exam – an exam in which the doctor, nurse, or other health care provider uses their finger to check for any abnormalities in the rectum (digital means fingers).

DNA – a molecule in the cell that carries genetic material.

Dominant inheritance – when one gene of a gene pair “dominates”, or has control over, the other gene. For example, if one gene of a gene pair has a mutation, this may cause the body not to work properly even if the other gene is just fine.

Environmental factors – elements from the surrounding environment that may act upon the health or life of a person.

Fecal Occult blood test –(fee-kul oh-kult) – a test used to look for blood in the feces that cannot be seen with the naked eye. This test is used to screen for colon cancer.

General Population – the whole number of people who live in a community.

Genes – structures found on the chromosomes that contain DNA. Genes come in pairs. A person gets one of each pair from their mother, and the other of each pair from their father.

Genetics – a branch of biology that deals with traits that are passed down from generation to generation.

Hereditary – related to genes being passed down from parent to child.

Lumpectomy – a surgical procedure to remove a lump from the breast.

Mammography – an x-ray of the breast to check for any abnormalities.

Mastectomy – a surgical procedure to remove the breast.

Menopause – the period in a woman’s life where she no longer experiences menstruation (her period), usually happening over the age of 40.

MRI – A test that is like an x-ray that can view body tissues, bones, and organs by making a 3-D picture.

Mutations – (mew-tay-shuns) a change in a gene that may make it work incorrectly.

Nucleus – (new-klee-us) -- the “control center” of the cell.

• **Pelvic exam** – an examination of the female reproductive structures (uterus, ovaries, vagina, etc.).

Predisposition – (pree-diss-poh-zi-shun) a greater chance to develop a condition than most other people. For example, if a person has a predisposition to cancer, this means that the person has a greater chance to develop cancer than most other people.

Preventive surgery – a surgery performed to prevent a disease, such as cancer, from occurring or spreading.

Prophylactic mastectomy – (pro-fih-lak-tik mas-tek-toh-mee) a surgery to remove the healthy breasts of women who are at a high risk of developing breast cancer.

Prophylactic oophorectomy – (pro-fih-lak-tik ooh-for-rek-toh-mee) a surgery to remove the healthy ovaries and Fallopian tubes of women who are at a high risk of developing ovarian cancer.

PSA blood test – a test that looks for special makers in the blood that may tell if a man has prostate cancer.

Screening – looking for evidence of a particular disease (such as cancer) in a person who is not showing any symptoms of the disease.

Sequencing – the process of examining the “chemical alphabet” or a person’s DNA.

Sigmoidoscopy – (sig-moyd-ah-sca-pee) an examination of a part of the large intestine using a long hollow tubular instrument.

Tamoxifen – (tuh-mox-ih-phen) -- a hormonal medication used to treat women who have had breast cancer. The drug is used to prevent the cancer from spreading and to reduce the chances of the cancer returning.

Ultrasound – a procedure that produces an image, like an x-ray, of the organs inside of the body to check for any abnormalities.

PROJECT 3

"Immune surveillance, stress and inherited susceptibility to breast cancer: a psychobiological analysis of the healthy daughters of breast cancer patients"

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Project 3: "Immune surveillance, stress, and inherited susceptibility to breast cancer: a psychobiological analysis of the healthy daughters of breast cancer patients"

Principal Investigator: Dr. Dana H. Bovbjerg

INTRODUCTION:

Mutations in the autosomal dominant breast cancer susceptibility genes (BRCA1/BRCA2), account for less than half the attributable increased risk of breast cancer among first degree relatives of breast cancer patients. We hypothesize that deficits in immune surveillance mechanisms may contribute to the currently unexplained familial risk, based on initial evidence of reduced NK cell cytotoxicity in women at familial risk for breast cancer. On the other hand, heightened stress levels in women whose close relatives have had breast cancer raise the possibility that the lower levels of cytotoxic activity may be due to stress-induced immune suppression, rather than inherited deficits in immune surveillance. Our research investigates these two possible nonexclusive explanations for variability in NK cell cytotoxicity. The study also examines the possibility that the daughters of breast cancer patients may evidence a broader pattern of alterations in immune function, since NK cells play a central role in multiple aspects of immune surveillance. In addition to their role as cytotoxic effector cells in innate immune defenses, stimulated NK cells are early producers of key cytokines, which are known to have independent anti-cancer effects and to play a major role in eliciting and shaping additional immune defenses against cancer. Recent research indicating genetic influences (e.g., polymorphism studies) on these two key cytokines (TNF α , IFN γ) suggests another powerful approach to exploring the contribution of these cytokines to familial risk of breast cancer. Our longitudinal study is based on the Case Control design of Project 1 in the Center, in that daughters of both Cases and Controls will be recruited to Project 3. The daughters of Cases and Controls (Project 1) constitute the two Study Groups (final N=150/group). Each participating Case-daughter is assessed (Core A) on two separate occasions approximately 3 months apart at the same time of day. At each assessment standardized self-report measures are completed and, following at least 20 minutes of quiet rest, a blood sample (30 ml) collected. Blood samples are assayed for immune function and cytokine genotypes (Core C). Routine statistical analyses (Core B) will test study hypotheses after anticipated sample sizes are achieved. If the results of the proposed research are consistent with the hypothesis that deficits in immune surveillance contribute to familial risk above and beyond effects of stress, the study could have profound implications for the eradication of breast cancer. Such results would raise the possibility that appropriate interventions to increase the activity of immune surveillance mechanisms in daughters at familial risk, including reduced stress-induced immune suppression, might delay the onset or even prevent the development of breast cancer.

BODY:

Having submitted a response to the most recent revision request required for HSRRB

approval in March 2003, we did not hear from Dr. Pranulis again regarding our approval status until August 2004. Thus, we have fallen further behind the timeline in our Statement of Work. We now propose to further adjust the Statement of Work, modifying the new Task added in October 2003: (Months 0-36: Successful application for HSRRB approval through the USAMRAA office). We anticipate having the requested Mt Sinai IRB approval back to her within the next month.

In the past year, we have completed the activities allowable in the absence of formal approval by the HSRRB, Task 1: Setting up of Project 3 procedures. We have established procedures for screening, recruiting and interviewing study participants with Core A. We have prepared self-report and immune measures. We have hired and trained a Research Coordinator to implement the study procedures as soon as formal approval is granted. With the preparations in place, we anticipate being able to complete all the proposed Tasks in a timely manner once we receive approval from the HSRRB of the USAMRAA. Because of the delayed start date, we now propose to modify the timeline amended in October 2003, to delay the start of Tasks 2-6 by an additional 12 months. Our proposed timeline for the Statement of Work is thus:

- | | |
|---------|---|
| Task -1 | Successful application for HSRRB approval through the USAMRAA office: Months 0-36 |
| Task 1 | Setting up of Project 3 procedures: Months 0-36 |
| Task 2 | Screening and recruitment of study participants: Months 36-60 |
| Task 3 | Inclusion of study subjects |
| Task 4 | Second assessment of study subjects |
| Task 5 | Data processing: Months 38-65 |
| Task 6 | Statistical analysis: Months 60-72 |

KEY RESEARCH ACOMPLISHMENTS:

At this point in the research, with no approval by the HSRRB of the USAMRAA, no results are yet available.

REPORTABLE OUTCOMES:

We have recently been awarded a grant that will recruit the "graduates" of Project 3, as a follow-up to examine the impact of an intervention demonstrated to be effective with other populations with a history of major life stressors, and current chronic stress.

Source:	Department of the Army
Grant Number:	BC031275

Project Title: Emotional, Biological and Cognitive Impact of a Brief Expressive Writing Intervention for African American Women at Familial Breast Cancer Risk

Project Period: 7/01/04-6/30/08 Total Direct Costs: \$548,393/First Year: \$135,623

P.I.: H. B. Valdimarsdottir

Co-P.I.: D. H. Bovbjerg

CONCLUSIONS:

At this point in the research, no results are yet available. If the results of the proposed research are consistent with the hypothesis that deficits in immune surveillance contribute to familial risk above and beyond effects of stress, the study could have profound implications for the eradication of breast cancer. Such results would raise the possibility that appropriate interventions to increase the activity of immune surveillance mechanisms in daughters at familial risk, including reductions in stress-induced immune suppression, might delay the onset or even prevent the development of breast cancer.

REFERENCES:

N/A

APPENDICES:

None

CORE A

"Recruitment, Tracking and Interviewing Core"

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CORE A: Recruitment, Tracking and Interviewing Core

Principal Investigator: Lina Jandorf, M.A.

INTRODUCTION:

This Core has the responsibility of contacting the identified cases, controls, and healthy adult daughters of the cases and controls, for participation in the three projects of this Center. Breast Cancer survivors are utilized as Patient Advocates for Research Participation (PARPS), that is, as recruiters. Once a case or control has been identified, she is contacted by an interviewer or PARP who schedules the first interview/ assessment.

Both PARPS and interviewers are culturally competent and have been fully trained. Training for the interviewers includes information on how to conduct each assessment/interview, to collect blood specimens, contact and conduct the telephone assessments for the Cases in Project 2 and the healthy adult daughters of both cases and controls for Project 3, instruct participants in the use of the ambulatory blood pressure monitor, and track their involvement across and within the project. At times, the interviewers will also serve as recruiters at designated clinic sites.

BODY:

Consistent with the Statement of Work, as of this reporting period, we have addressed four major tasks. The first involves the contact of identified cases and controls by PARPS. Fourteen PARPS have been recruited and trained. A recruiter manual (see appendix) has been developed and is continually updated. Second, in order to complete each interview or assessment, as outlined in the Overall Program, Research Interviewers have been hired and trained to complete the interviews/assessments for each Protocol. A manual for use by interviewers has been completed (see appendix) and is also updated as required. Since receiving HSRRB approval for Project 1, we have recently begun the actual field work. For Project 1, we started contacting Controls from the random digit dialing (RDD) company. The third task for this Core regards the education of physicians at the cooperating hospitals. We have made contact with the cooperating hospitals and key staff at each location has been identified. Meetings have been conducted and standard procedures for the identification of cases have been established. Our Interviewers are on-site at each cooperating hospital to assist with recruiting. In addition, we have worked with the Patient Navigators/Research Nurses at the cooperating sites to ensure that they are aware of our procedures. Finally, this Core has the responsibility of tracking all of the participants in Projects 1, 2 and 3. Working with Core C, the tracking database has been completed. As we begin recruitment, we will continue to update the database and modify it as needed.

KEY RESEARCH ACCOMPLISHMENTS:

There are no results available at this time.

REPORTABLE OUTCOMES:

There are no results available at this time.

CONCLUSIONS:

At this point in the research, no results are available. We have, however, in place all of the tools (assessments, tracking database, trained recruiters and interviewers) necessary to conduct the research and to begin to interview study participants.

REFERENCES:

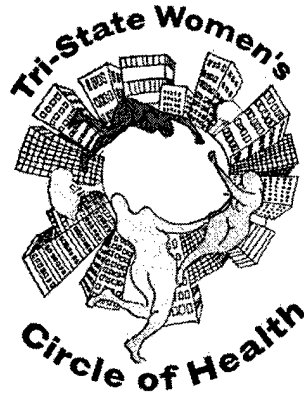
There are no additional references to report at this time.

APPENDICES:

Copies of both the Recruiter and Interviewer Manuals are included.

CORE A APPENDIX

**INTERVIEWER TRAINING MANUAL
RECRUITER TRAINING MANUAL**



Breast Study

Interviewer Training Manual

10/14/04

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I.

STUDY DESCRIPTION

Description of Breast Cancer Study

Protocol Summary

About the Studies

Tri-State Women's Circle of Health Protocols

Flow Chart

DESCRIPTION OF BREAST CANCER STUDY

More and more women are being diagnosed with breast cancer. One out of every eight women will develop breast cancer in her lifetime. African-American women often develop breast cancer at an early age (before age 50) and sometimes the disease is more serious than in Caucasian women. For Hispanic women, breast cancer is the most commonly diagnosed cancer. This research project is to help us understand the causes of breast cancer. What people eat and drink and other lifestyle habits could affect their health. But not everyone with similar habits will get sick. This may be because of differences in how their bodies respond to things that they eat, drink, and smoke; and medications they take. In these studies, we will ask the same questions of women with breast cancer ("Cases") and women without cancer ("Controls"), who are the same age and live in the same area. They will be asked questions about eating, drinking, exercise and smoking habits, their medical and family histories, and other behaviors which may protect against or otherwise affect disease. Measurements will be taken, including height and weight. Comparisons between women with breast cancer and those without cancer will then be undertaken to determine differences.

Blood will also be drawn, (about 2 tablespoons). This blood will be processed to measure differences in how the body deals with things we eat, drink and smoke. Just like the answers to the questions, ways in which people break things down will also be compared between women with breast cancer and those without. From this study we hope that we will be able to see what some of the causes of breast cancer might be.

10/14/04

Reference: Study Description

Tri-State Women's Circle of Health

PROTOCOL SUMMARY FOR NEW AND CONTINUING PROTOCOLS

1. Provide a brief (200-250 word) summary of background information for physician/scientists:

African-American women are more often diagnosed with breast cancer at an early age and have more aggressive disease. They are also more likely to experience menarche at an earlier age and to have higher estrogen levels. We hypothesize that earlier, more aggressive disease is related to earlier menarche and to lifetime hormonal exposures, and that both breast cancer risk and age at menarche are related to genetic, behavioral and reproductive factors. In a case-control study, we will evaluate relationships between breast cancer risk and a number of risk factors that will affect hormonal levels in African-American (e.g., lifetime physical activity patterns, alcohol consumption, smoking, diet, weight and weight change throughout the life, early life events, and hormonal and reproductive factors). Data will be collected through an in-person interview. We will also evaluate interindividual differences in hormone metabolism by studying genetic polymorphisms in enzymes in estrogen metabolism. The same factors, childhood body size, physical activity and early stressful events will also be evaluated in relation to age at menarche. We will identify African-American women with incident breast cancer at hospitals in NYC with the largest referral patterns for African-Americans, and controls using random digit dialing. Both cases and controls will be recruited (n=1600) by culturally-sensitive breast cancer survivors. In-person interviews will be conducted and a blood specimen drawn. Statistical analyses will be performed to address each of the aims. There are few data to explain the earlier incidence of breast cancer and more aggressive disease among African-Americans, and results from this study will elucidate the probable link between breast cancer risk, early age at menarche and hormonal milieu, and the factors that predict them. In addition, to support our research on this topic we propose to collect preliminary data from 100 Caucasian breast cancer patients and matched controls (n=100), as well as 100 Hispanic breast cancer patients and matched controls (n=100).

2. State purpose of study:

The objectives of this molecular epidemiologic case-control study are to:

- 1) Evaluate relationships between breast cancer risk and a number of behavioral, reproductive and hormonal factors in African American women. An interview will be conducted with 800 women with breast cancer and 800 healthy controls, assessing lifetime physical activity patterns, alcohol consumption, smoking, diet, weight and weight change throughout the life, early life events, and hormonal and reproductive factors.
- 2) Evaluate the role of genetic variability in steroidogenesis and hormone metabolism on breast cancer risk and as a modifier of other risk factors by collection of a blood specimen, DNA extraction, and genotyping for polymorphisms in: CYP17, CYP19, CYP3A4, CYP1B1, CYP1A1, COMT, MnSOD, and UGT1A1. Main effects of the polymorphisms will be evaluated, as well as gene/environment interactions.
- 3) Determine the extent to which age at menarche is predicted by childhood body size and physical activity, stressful events in early life, and genetic polymorphisms in enzymes involved in steroidogenesis and hormone metabolism (CYP17, CYP3A4, CYP19, CYP1B1, CYP1A1).

Evaluate whether specific exposures, particularly early age at menarche, and/or genetic polymorphisms in hormone metabolizing enzymes, as well as gene/gene and gene/environment interactions, are related to earlier onset of breast cancer and more aggressive disease (delineated by stage, grade, ER/PR status, mitotic index).

3. Indicate number of subjects to be enrolled at this site: 165 African American, 80 Hispanic, and 80 White women with breast cancer over a 3-year period.

Indicate total number of subjects to be enrolled, if multicenter study: 1600 African American women (800 with breast cancer and 800 controls), 200 Hispanic women (100 with breast cancer and 100 controls), and 200 White women (100 with breast cancer and 100 controls)

4. Indicate the characteristics of study population:

(a) Gender:	Males	yes _____	no <u>X</u> _____
	Females	yes <u>X</u> _____	no _____
(b) Age range:		from <u>20</u> _____	to <u>64</u> _____
(c) Racial and Ethnic Groups:			
	Caucasian	yes <u>X</u> _____	no _____
	Black	yes <u>X</u> _____	no _____
	Hispanic	yes <u>X</u> _____	no _____
	American Indian	yes _____	no <u>X</u> _____
	Alaskan Native	yes _____	no <u>X</u> _____
	Asian/Pacific Islander	yes _____	no <u>X</u> _____
	Other (specify) _____		

(d) Justify any exclusion of specific gender, age, and racial or ethnic groups:

This study is designed to specifically focus on breast cancer in women.

Men are excluded because breast cancer in men, a rare disease, is likely to have different risk factors than breast cancer in women.

Children (those under age 20) are excluded for similar reasons. While breast cancer does rarely occur in women under 20, the risk factors and nature of the disease are likely to be different than that in older women. Incorporation of these two groups (men and women under 20) would likely introduce too much heterogeneity into the study population and mask associations. Women over age 64 are excluded because Control participants who are older than 64 can no longer be identified through Centers for Medicare and Medicaid (CMS) rosters. CMS has recently imposed a moratorium on the release of this data for use in research studies. Appropriate alternative recruitment strategies have yet to be established in the literature. To recruit Controls under the age 65, we are using Random Digit Dialing (RDD), however, experience has shown that this methodology works very poorly among older women, and response rates are very low. More importantly, because the study focuses on elucidating reasons for the diagnosis of breast cancer at an earlier age among African-American women, the inclusion of women up to age 64 will be sufficient to address these hypotheses.

5. State inclusion criteria for enrollment in study:

Cases will be African American, Caucasian, and Hispanic women between the ages of 20 and 64 who have newly diagnosed primary, incident, histologically-confirmed invasive or in situ breast cancer.

'African-American' will be those who self-identify as Black or Negro, consistent with guidelines of the New York State Tumor Registry, and with 1990 U.S. Census guidelines.

Controls will be African-American, Caucasian, and Hispanic women with no history of breast cancer, but who meet the other criteria as cases.

6. State exclusion criteria for enrollment in study:

Patients with a history of any cancer other than non-melanoma skin cancer are excluded, as are women with a documented or self-reported history of significant memory deficit. Cases must have a residential telephone. Exclusion criteria for controls are the same as for cases.

7. Will vulnerable subjects be enrolled in this study? yes X no
- (a) Individuals with diminished mental capacity yes no X
- (b) children yes no X
- (c) pregnant women yes X no
- (d) fetuses yes no X
- (e) economically or educationally disadvantaged persons yes X no
- (f) prisoners yes no X

8. If vulnerable subjects are to be enrolled, describe the special precautions that will be taken to ensure that consent is freely given and that the rights and welfare of the subjects are protected:

Participation is voluntary. All subjects will be treated equally. Minor incentives will be offered (a \$25.00 gift certificate). Participants will also be reimbursed (e.g., roundtrip metrocard) for travel expenses that they incur as part of their participation in this study. However, there will be no payment for participation. Since there is no danger to fetuses, pregnant women will not be excluded.

9. If the study involves children, will the MSSM Certification of Assent form be used to document that assent was freely given without coercion? yes _____ no N/A
If no, indicate how assent will be documented:

10. Indicate where and how research data will be stored to ensure confidentiality:

Procedures assuring confidentiality of data and samples will be followed, including labeling of all questionnaire data and biological samples with study ID only, and password-protection of computer data. From the time of interview, the participant will be referred to by ID number only. Identifiers will be stripped from all data, and codes linking those numbers to individuals, as well as signed consents, will be kept in a locked file to which only key personnel have access. Data will be analyzed in group aggregates only, and results reported only for by the entire case and control groups.

11. Will data (e.g. records, samples, specimens, databases, surveys, etc.) be obtained with identifiers that can be directly or indirectly linked back to the subjects?
yes X no

12. Will data (e.g. records, samples, specimens, databases, surveys, etc.) be stored with identifiers that can be directly or indirectly linked back to the subjects?
yes X no

13. Indicate who will have access to information about the subjects that is identifiable:

Key study personnel (principal investigator, project director, recruiter, interviewer) will have initial contact with study participants. However, no names will be attached to any identifiable data after it is collected. A file linking data to individuals will be kept separately and available only to the principal investigator.

14. Indicate how potential subjects will be identified and recruited for participation in the study:

Breast cancer cases will be identified by physician referral from participating physicians and surgeons. Eligible patients will be recruited in one of two ways: 1. Women identified as cases will be informed of the study by their surgeon or clinical staff member at a convenient time during an office/clinic appointment. Patients responding with interest in the study will be asked if they would like to be introduced to a member of the research team, who will describe study goals and discuss the study procedures. 2. A member of the study team will communicate regularly with staff members of participating surgeons offices on a pre-determined basis (e.g., weekly) to obtain the name of any newly diagnosed breast cancer cases not previously approached about participating in the study. The physician of the potential participant will be contacted to confirm the diagnosis and diagnosis date, obtain consent to contact his/her patient and acquire contact information (e.g., home address). After confirmation and physician consent, a letter signed by their doctors (see attached) will be sent to patients briefly describing the study, along with a brochure regarding the study and contact information (e.g., phone number) to use if they are interested in learning more about participating in the study. Patients responding with interest in the study will then be mailed an introductory postcard with a photograph of their recruiter, explaining that she is a breast cancer survivor, and will be calling soon to discuss the study. During the subsequent phone call, the recruiter will describe study goals and discuss the study procedures. A letter of invitation will be mailed to women who cannot be reached by telephone (see attached). African-American, Caucasian, and Hispanic breast cancer survivors will be trained as recruiters for this study (Patient Advocates for Research Participation (PARP)).

Approximately 1,200 potential controls will be identified and frequency matched to cases on the expected breast cancer case distribution (based on 1993-1997 data from the NY State Tumor Registry) by 5-year age groups and county of residence. Eligibility criteria will be the same as for cases, with the exclusion of breast cancer. Women will be identified using random digit dialing (RDD). The telephone exchanges (area code plus first five digits) of the breast cancer cases receiving medical care at the participating hospitals will be used for sampling. Women indicating an interest in participating will receive the brochure describing the study, and an introductory postcard from the recruiter with a photograph of themselves to the potential participant, explaining that she is a breast cancer survivor and will be calling soon to discuss the breast cancer study. This card will be followed up by a phone call from the recruiter, who describes study goals and discusses the study procedure. A letter of invitation will be mailed to women who cannot be reached by telephone.

All women who participate in the study will be offered a \$25 gift certificate to Rite Aid Pharmacies or Pathmark Grocery Stores. For women who have agreed to participate, but have had difficulty scheduling an interview or keeping their appointments, an increase in the amount of reimbursement (\$50 gift certificate) will be offered. A second consent form (Consent Form

B) with the increased reimbursement will be presented to these women since their lives are so busy and their time is more costly. Participants will also be reimbursed (e.g., roundtrip metrocard) for travel expenses related to their participation in this study. A thank you note will be mailed to participants following their interview (see attached).

15. Indicate when and where consent will be obtained:

The consent will be reviewed with the participant at the outset of the in-person interview. After responding to any questions the participant may have, informed consent will be obtained.

16. Indicate how you will determine whether the subjects (or their surrogates) understand the information that was provided in the consent document:

The interviewer will review the consent form with the participant and ask if they understand it and if they have any questions.

17. Will the study include medical record review (hard copy of record or via computer)?
yes X no

If yes, list those individuals (e.g. co-investigators, fellows, research nurses, research coordinators, pharmaceutical company protocol monitors, etc.) who require access to the record:

<u>Title</u>	<u>Dept./Institution/Company</u>
Project Director	Department of Oncological Sciences, MSSM
Research Assistants	Department of Oncological Sciences, MSSM
Research Nurse	Cancer Center, Queens Hospital Center

18. Summarize, in a narrative what actually will be done to the subjects during their participation in the study. Make certain that the following are included:

- (a) a clear description of what is being done for research purposes and what is being done as part of standard clinical care;

None of the procedures to be employed in this protocol are done as part of clinical care; all are for research purposes. Subjects will be interviewed in their homes or at another agreed-upon location. The interview will contain questions regarding lifestyle, reproductive, hormonal and demographic factors. A blood specimen (30 mL) will be obtained by a member of the study team or, if the participant prefers, by her physician. In the event that the woman prefers that her doctor draw blood, tubes with ID labels will be provided with a self-addressed overnight mailer and instructions for handling. A saliva (mouthwash) specimen will be obtained from participants who are unable to provide a blood sample.

- (b) a list of tests and procedures that will be performed for research purposes (e.g. blood tests, urine tests, cultures, interviews, questionnaires, surgical procedures, cardiac catheterization, pulmonary function tests, X-rays, scans, etc);

As described above, an interview will be administered to obtain information on known and suspected breast cancer risk factors. We will obtain demographic

information, as well as information on reproductive and hormonal factors, such as age at menarche, age at first full-term pregnancy, age at menopause, oral contraceptive use, and hormone replacement therapy for postmenopausal women. For women with children, we will also inquire about breastfeeding practices. Information will be collected on presence of cancer in first-degree relatives. We will ask about physical activity and body size throughout the life span, as well as smoking and alcohol consumption. A brief food-frequency questionnaire will also be administered. Because we are hypothesizing that early childhood stressful events can result in early menarche, we will also administer a validated questionnaire regarding life events in the years preceding puberty.

A 30 mL blood specimen will be obtained and from it, DNA will be extracted and evaluated for genetic polymorphisms in specific genes involved in the metabolism of steroid hormones. These are genetic variants that are prevalent in the population (greater than 10% in our study), and that are not known to infer risk of disease in the absence of other moderating factors. They include: CYP17, CYP19, CYP3A4, CYP1B1, CYP1A1, COMT, MnSOD, and UGT1A1. A saliva (mouthwash) specimen will be obtained from participants who are unable to provide a blood sample. A breast tumor specimen will also be obtained for future studies of molecular tumor characteristics.

- (c) a brief description of the analyses that will be performed on the biologic or non-biologic (i.e. questionnaires) samples collected;

The above listed genes will be subjected to allele-specific PCR to determine variant genotypes. Questionnaire data will be coded, entered into a database, cleaned, and variables of interest created. These will be evaluated as risk factors for breast cancer by comparing between cases and controls. Similarly, the effect of variant genotypes will also be tested using contingency tables and chi-square test statistic. The magnitude of risk associated with factors found to be significantly different between cases and controls will be estimated using unconditional logistic regression, adjusting for possible confounding variables. Gene/gene and gene/environment interactions will be calculated by performing stratified analyses, case-series analyses in which exposures are regressed on genotype status, reflecting the degree to which an exposure is associated with case status among those with 'low-risk' vs. 'high-risk' alleles. Interactions between genes and other factors that are thought to work together biologically will also be examined with cross-product terms in the logistic models. Dummy variables representing high-risk alleles and exposures they may modify will be entered into the regression and we will model the nature of the joint association. We will also evaluate the predictive role of a number of variables on age at menarche as the outcome variable. Finally, in cases only, we will categorize disease by degree of aggressiveness, and use techniques of logistic regression to estimate strength of association between another of predictive factors and markers of more aggressive disease.

- (d) a list of investigational drugs that will administered and indicate for each whether there is an IND or there is an application to the FDA for an IND;

No investigational drugs will be administered.

- (e) a list of investigational devices that will be used, indicate if they are classified as significant risk (SR) or non-significant risk (NSR) devices and whether there is an IDE or there is an application to the FDA for an IDE if the device is SR;

No investigational devices will be used.

- (f) a statement that defines who will be financially responsible for the costs associated with participation in the study (e.g. examinations, procedures, drugs, devices, etc.) and a statement that defines what will be provided without cost to the subjects;

Costs associated with this study will be the responsibility of the PI, and there will be no expense to the subjects. In fact, they will receive \$25 remuneration for their time given to the study. Participants will also be reimbursed for travel expenses related to their participation in this study.

- (g) your assessment of whether the research involves any physical, psychological, social and/or economic risk(s) and the magnitude of the risk(s);

There will be little discomfort and risk from providing the blood specimen. In a small number of people, it is possible that some bruising may occur where the needle was inserted for the blood draw. There is also a slight possibility that infection could occur, although this is rare due to all of the precautions taken. Some people may be made uncomfortable by some of the personal questions, and it is possible that trying to recall events in the past may frustrate some participants. There may be concerns regarding confidentiality, particularly with the genotyping data; it is stressed to the participant that all information is coded by ID number only, no names will be associated with results, and only key investigators have information that could link the participant with their data.

- (h) your assessment of the risk/benefit ratio of the research;

Participants are given a \$25 gift certificate as compensation. It is likely that important information will be obtained in this study that could greatly benefit society. Risks are minimal, and society may benefit from the results of the study.

19. Will the study be monitored?

yes _____ no X

If yes, indicate the frequency of monitoring, specify who will do the monitoring (e.g. regulatory monitors, an external data and safety monitoring board (DSMB), a DSMB composed of local individual(s) unaffiliated with the study and indicate to whom monitors will report in addition to the investigator (e.g. NIH, FDA, industry sponsor, IRB).

NOTE:

a) Data and patient safety monitoring: if required, a Data and Safety Monitoring Board (DSMB), which must be convened by the PI, can be made up of internal and/or external members who have the appropriate expertise and are totally independent of and unaffiliated with the study. The composition of the DSMB should be commensurate with the complexity of

the proposed study and will be reviewed by the IRB. Approval of the DSMB by the IRB is required prior to initiating the clinical trial.

b) Regulatory monitoring: if required, independent regulatory monitors must be provided by the sponsor of a project. If the PI is also the sponsor, then it is the responsibility of the PI to obtain monitors. Monitors may be MSSM personnel with the requisite expertise (documented by their curriculum vitae and approved by the IRB) or external monitors (the IRB can assist in identifying external monitors), who are not directly affiliated with the proposed study.

20. Does the principal investigator or any of the co-investigators have a potential financial conflict of interest in relationship to this study? yes _____ no X

If yes, describe the nature of the potential conflict for each investigator.

21. Will research coordinators be employed for this study? yes x no _____

a) How many coordinators will be employed for this study? 1

b) Will the coordinator(s) work full time on this one project? yes _____ no x

If no, indicate if the coordinator(s) will work on other projects and describe the time allocation (in hours/week) of each coordinator.

The research coordinator will also work as Field Coordinator for GCO#02-0521 Race & Risk Factors for Early/Aggressive Breast Cancer. As this study is an expansion of the current study, there will be little differentiation in the time allocated for one study versus the other.

c) Provide the name(s) of the coordinator(s) (if known) and indicate the number of subjects each coordinator will follow in this study.

Senaka Peter, MPH, is the coordinator for this study. She will work with the team of research recruiters and interviewers in Core A (Recruitment and Interview Core of the Center) to facilitate the identification and recruitment of 2000 participants over three years.

d) If more than one coordinator will be employed for this study, indicate the name of the senior coordinator n/a

e) Provide a contact telephone number for the senior coordinator (212) 659-5406

f) If the research coordinator(s) will work on other projects indicate the total number of other projects each coordinator will work on, the number of subjects they will follow in each protocol, provide the name of the PIs and the GCO numbers other projects.

The research coordinator will work on two projects: the current study (GCO#00-0730) and GCO#02-0521 Race & Risk Factors for Early/Aggressive Breast Cancer (PI: Christine Ambrosone, PhD). This study is an expansion of the on-going case-control study. As Field Coordinator for GCO#02-0521, she will work with a PhD-level Project Director, research assistants, interviewers, and the participating physicians and their staff to facilitate the identification and recruitment of 3200 participants over five years.

g) Indicate if the individual(s) has prior experience as a research coordinator and briefly describe that experience. Include completed course work and credentials. If none, indicate your plans to formally educate and train the individual as a research coordinator.

Senaka Peter has a Master of Public Health degree and has had experience as a research coordinator in clinical and behavioral research studies. She has been the research coordinator for Project 1: Behavior, estrogen metabolism, and breast cancer risk: A molecular epidemiologic study of GCO#00-0730 Genetic Factors in Breast Cancer: Center for Interdisciplinary Biobehavioral Research for two years. As research coordinator she will primarily deal with data collected through interview.

22. Will private medical/psychiatric information be requested (e.g. in questionnaires) about individuals other than those who are the subjects who are enrolled in the study (e.g. family members)?
yes X no

a) if yes, describe the topics that will be covered.

Family History of Cancer

b) for each topic indicate whether or not the questions would be considered part of a routine, complete medical history as would be obtained for standard clinical care.

The information that we request is information that would be gathered as part of standard clinical care during a complete and routine query of an individual's family medical history.

10/14/04

Reference: Study Description

ABOUT THE STUDIES

“Core A” is the name of the Recruiting and Interviewing portion of the three research projects, each of which addresses an important issue in breast cancer research.

Principal Investigator: Lina Jandorf, M.A.

These 4-year studies looking at critical psychological or behavioral issues will improve our understanding of the causes of breast cancer. The studies are:

Project 1: “Behavior, estrogen metabolism, and breast cancer risk: a molecular epidemiologic study.” Principal Investigator: Christine Ambrosone, Ph.D.

This is a study to understand why some women get breast cancer and others do not.

Project 2: “Impact of culturally tailored counseling on psychobehavioral outcomes and BRCA decision making among African-American women with breast cancer.” Principal Investigator: Heiddis Valdimarsdottir, Ph.D.

Women from Project 1 whose family history suggests that their cancer may be inherited will be offered genetic counseling and genetic testing at no cost. Such counseling may reduce distress and increase knowledge about breast cancer, genetic testing, and breast cancer prevention and surveillance options.

Project 3: “Immune surveillance, stress, and inherited susceptibility to breast cancer: a psychobiological analysis of the healthy daughters of breast cancer patients.”
Principal Investigator: Dana Bovbjerg, Ph.D.

The adult daughters of women with breast cancer from Project 1 will be compared with the adult daughters of women without breast cancer to examine the possibility that inherited deficits in the immune system may be related to familial risk among daughters of patients whose cancers are not related to mutations in BRCA1 or BRCA2 genes.

10/14/04

Reference: Study Description

Tri-State Women's Circle of Health

Protocol	DOD GCO#00-0730	DOD – MSSM GCO#00-0730 (0002)
Study Population	800 CA – Black (Hisp who ID as Black) 800 CO - RDD	800 CA – Black 100 CA – White 100 CA – Hisp 800B, 100W, 100H CO - RDD
Hospital	All Hospitals	All Hospitals
Age Range	20-64 years	20-64 years
Eligibility	<ul style="list-style-type: none"> ▪ CA: Primary, incident, histologically confirmed invasive/in situ ▪ CA: telephone ▪ CO: No prior history of CA ▪ English only 	<ul style="list-style-type: none"> ▪ CA: Primary, incident, histologically confirmed invasive/in situ ▪ CA: telephone ▪ CO: No prior history of CA ▪ English only
Reimbursement	\$25 GC	\$25/\$50 GC
Contact & Recruiting	<ul style="list-style-type: none"> ▪ New cases: MDs/clinical staff introduce study during visit ▪ If interested, introduced to RA at clinic/office hours or ▪ MD asks permission to release contact information ▪ Interviewer telephones to recruit ▪ Interview scheduled 	<ul style="list-style-type: none"> ▪ ID through physician referral at hospital/private doctor's offices ▪ New cases: MDs/clinical staff introduce study; if interested, introduced to RA, or ▪ Contact MD, get consent to contact & contact info ▪ RA sends letters, puts in tracking d-base ▪ Letter from doc w/ brochure ▪ Pts responding with interest receive PARP postcard ▪ PARP protocol-PPC ▪ Interview scheduled

10/14/2004

Reference: Study Description

TRI-STATE CIRCLE OF HEALTH FLOW CHART

	Subject Identification	Eligibility Confirmation	Materials	Recruitment	Informed Consent	Interview Process	Questionnaire Review
Hospital Cases	MD or staff	<ul style="list-style-type: none"> MD or staff 9 month post-diagnosis time frame will be tracked through Eligible Applicants Data Base maintained by Project 1 (SP) 	Brochure given by MD or staff	<ul style="list-style-type: none"> Recruitment form completed by MD/staff/ interviewer on-site Interviewer schedules interview 	obtained either by MD staff or Interviewer on-site, or at the time of interview by the Interviewer	Core A-- appointment confirmation, lab notification, interview, recruitment for additional studies, tracking of scheduling and specimens pending	Core A (Interviewer) and Project 1 (SP)
RDD Controls	phone list	RDD Company	Brochure, letter, and Recruiter Post-card mailed by Core A	<ul style="list-style-type: none"> Recruiter assigned by Core A Recruiter schedules interview 	obtained by the Interviewer at the time of interview	Core A-- appointment confirmation, lab notification, interview, recruitment for additional studies, tracking of scheduling and specimens pending	Core A (Interviewer) and Project 1 (SP)

10/14/04

Reference: Study Description

II.

ROLE OF THE RECRUITER

Sequence of Subject Recruitment

Control Contacts

Case Contacts

Refuser Questionnaire

10/14/04

Sequence of Subject Recruitment

1. Cases are identified by:
 - Physicians or their staff directly
2. Controls are identified by:
 - General public controls are identified by an RDD (random digit dialing) company through phone lists
3. Cases are recruited by Physicians' staff directly after their initial diagnosis. Informed consent may be obtained and blood drawn at that time.
4. Controls are assigned to recruiters. Packets are given to recruiters and include:
 - Contact sheets
 - Scripts for phone call
 - Reimbursement forms
 - Self-addressed stamped priority mail envelopes from MSSM
 - Refuser Questionnaires
5. For controls a letter, brochure and post-card with the recruiter's picture and name will be sent by MSSM staff.
6. Recruiter will contact subjects within 14 days if possible.
 - At any time, recruiters may call MSSM staff for assistance with subject phone numbers that may be incorrect. Interviewer will attempt to find current phone number and advise recruiter.
7. Recruiter notifies interviewer of interview date and location by phone or e-mail and interviewer forwards travel directions to participant.
8. Recruiter returns the completed contact sheet back to MSSM.

10/14/04

Reference: Role of the Recruiter

Date assigned _____

Date to notify MSSM staff
& return contact sheet

Date recruiter returned
contact sheet to MSSM

**MSSM BREAST CANCER RESEARCH
CONTROL CONTACT SHEET**

ID NUMBER: _____ REFERENCE DATE _____ AGE: _____

PARTICIPANT'S NAME: _____

PHONE NUMBER: _____ ETHNICITY: _____

PARTICIPANT'S ADDRESS: _____

BEST DAY TO CALL: _____ BEST TIME TO CALL: _____

REFERRED BY: RDD _____ HOSPITAL _____ (NAME)

RECRUITER'S NAME: _____

INTERVIEWER'S NAME: _____

SCHEDULED INTERVIEW DAY: _____ DATE: _____ TIME: _____

ATTEMPTS

Date	Time	Comments	Participation		Meeting Place		
			Yes	No	Home	Hospital	Other

Recruiter, please check the following words that apply to the participant you called. Also write down any additional comments that the participant made or your feelings about your conversation.

- | | | |
|--|------------------------------------|--|
| <input type="checkbox"/> Enthusiastic | <input type="checkbox"/> Nervous | <input type="checkbox"/> Not sure if they want to participate |
| <input type="checkbox"/> Excited | <input type="checkbox"/> Hesitant | <input type="checkbox"/> Would like more information about the study |
| <input type="checkbox"/> Willing to help | <input type="checkbox"/> Angry | <input type="checkbox"/> Questions for staff about the study |
| <input type="checkbox"/> Pleasant | <input type="checkbox"/> Depressed | |

Additional Comments: _____

If Answering Machine: "I'm calling regarding a study at Mount Sinai and I will call back (specific time) or you may reach Senaka Peter at Mount Sinai by calling 1-866-223-2219 or 212 659-5406."

10/14/04

Reference: Role of the Recruiter

ID NUMBER _____

REFERENCE DATE _____

Please attempt to call subjects at least once between 9-11a.m.; 1-5p.m.; and 7-8 p.m. before determining whether you can reach them. Please attempt to contact this subject at least 5 times before _____. (return date)

PARTICIPANT RECRUITMENT FORM
[FORM FOR CONTROLS, WOMEN WITHOUT BREAST CANCER]

Hello, may I speak with _____
(WOMAN'S NAME)

If she is not there "When would be a better time to reach her, or is there a better number? I am trying to follow up on some information sent to her about a study at Mt Sinai School of Medicine."

(ONCE WOMAN IS ON THE PHONE):

Hello, my name is _____. I'm a volunteer involved with outreach for the Mount Sinai School of Medicine. A while back, you received a phone call regarding Dr. Christine Ambrosone's breast cancer research. At that time, you agreed to be called to learn more about an on-going study about breast cancer and that is why I'm calling today. Do you remember receiving information about the study, as well as a postcard from me, in the mail? Do you have five minutes to talk? If you have time now, I would like to tell you more about it.

If no:

ASK FOR A BETTER TIME TO CALL BACK. TIME: _____ Day of the Week: _____

If yes:

Before we go on, it is important that you know we are only looking for women who have not had any form of cancer other than minor skin cancers. If you feel that this describes you, we can go on. Should I continue? (Note to Recruiters: We are looking for women who have not had any cancer other than basal cell or squamous cell skin cancer)

If no:

Would you be willing to tell me why you think this does not describe you? **(IF WILLING, WRITE DOWN THE ANSWER ON THE CONTACT SHEET.)**

Well, since you do not think that you are eligible for the study, we do not need to take any more of your time. Thank you for being willing to hear more about the study. If you want any more information about the study, I would be glad to answer your questions if I can, or you can always check the website for the study, which is listed on the brochure you received in the mail. The website also has information links about cancer care and treatment.

If yes, they have not had any cancer other than the above skin cancers:

I would like to verify that you live in New York City six or more months out of the year. (If they ask why, explain that in order for our results to scientifically be valid, participants must reside in NYC six or more months out of the year.)

If no, let them know they do not qualify for the study and thank them for their time.

If yes, then continue:

I'll just take a minute to give you some background information: Doctors and researchers are concerned, because breast cancer is becoming more common, and not much is known about what causes it or how to prevent it. Scientists at Mount Sinai are running a study to try to learn some of the causes of breast cancer. This study will compare women who have had breast cancer to women who have not, to learn why some get cancer and others do not.

I want to tell you right at the start that there is no cost to you. In fact, you will receive a \$25 gift certificate to either Pathmark or Rite Aide as our way of thanking you for participating in our study. And I want you to know that your privacy is always protected. Only limited study personnel will be aware of your name. From the time of the interview, only an identification number that has been assigned to you will be used, not your name. Do you have any questions for me so far?

I would like to schedule an appointment for you to meet with a female interviewer from Mount Sinai at one of our interview sites and we will, of course, provide a Metrocard to cover travel expenses. At the interview, you will be asked questions about your diet, health history, and other lifestyle habits. Also, a small blood sample and body measurements, such as height and weight, will be taken. This will probably take about two hours. You will NOT be asked to take any drugs or submit to any procedures other than those we have described. We conduct interviews in many locations throughout the city. I'm sure we can find a location near you, or else we can, of course, come to your home, if you would prefer. Do you have any questions?

(IF THEY HAVE QUESTIONS THAT YOU DO NOT KNOW THE ANSWER TO, TELL THEM AN INTERVIEWER WILL CALL BACK TO ANSWER THEIR QUESTIONS).

Do you think you would be able to participate in this study? (YES)_____ (NO)_____

(IF NO, TRY TO FIND OUT WHY AND TRY TO RESPOND TO HER CONCERNS. IF IT WOULD HELP, REFER TO Q&A NUMBER 5 REGARDING CANCER HISTORY. IF THEY STILL SAY NO, ASK):

May I ask you just a few short questions about your socioeconomic background and medical and reproductive history on the phone? The information you would provide will help the researchers to determine whether there is a difference between the women who agree to participate in the study and those who do not agree to participate. Your name will not be attached to your comments and I will be the only person who knows who says what. You can decide not to answer any question you don't like at any time.

Do you agree to participate in this short telephone survey? (YES)_____ (NO)_____

(If YES, See Refuser Questionnaire)

(IF THEY AGREE TO PARTICIPATE, SAY):

That's great. I will be happy to set up an appointment for you. Which borough would you prefer?

☐ Manhattan – we have 3 locations:

- ☐ On the Upper East Side: **Mount Sinai Research Center**-- 98th Street and 5th Avenue
- ☐ On the West Side: **St. Luke's Roosevelt Hospital**-- 59th Street and 9th Avenue
- ☐ and downtown at **Beth Israel**—14th Street on Union Square

- ☐ Queens – **Queens Hospital Center**-- 164th Street in Jamaica
- ☐ Brooklyn – **Kings County Hospital** – 451 Clarkson Avenue
- ☐ The Bronx – **Weiler/Einstein Hospital** – 1695 Eastchester Road
- ☐ Participant's Home

Recruiter will check which is the selected location.

DAY INTERVIEW SCHEDULED: _____ DATE: _____ TIME: _____

I will let the Interviewers know you are interested in being in the study, and one of them will call to confirm the interview appointment. Is this the best phone number at which to reach you?

(IF YES, WRITE DOWN THE PHONE NUMBER THAT YOU CALLED.
OR, IF THERE IS A BETTER NUMBER, WRITE IT DOWN HERE).

(_ _) _ _ - _ _ _ Is there a good time of day to call you? **TIME:** _____.

Ok, so one of our Interviewers will be calling you soon to confirm your interview appointment and send you complete directions:

on _____ (**Date**) at _____ (**Time**) and she'll be meeting you at:

Home: _____ **Hospital:** _____ **Other:** _____

If you should want to speak with someone before the Interviewer calls, let me give you our phone number: 866-223-2219 or 212-659-5406. Thank you so much for your time, and for agreeing to be in this important study.

10/14/04

Section: Recruitment Tools/Techniques

Date assigned

Date to notify MSSM staff
& return contact sheet

Date recruiter returned
contact sheet to MSSM

MSSM BREAST CANCER RESEARCH CASE CONTACT SHEET

ID NUMBER: _____ REFERENCE DATE _____ AGE: _____

PARTICIPANT'S NAME: _____

PHONE NUMBER: _____ ETHNICITY: _____

PARTICIPANT'S ADDRESS: _____

REFERRED BY: MD _____ HOSPITAL _____ (NAME)

RECRUITER'S NAME: _____

INTERVIEWER'S NAME: _____

SCHEDULED INTERVIEW DAY: _____ DATE: _____ TIME: _____

ATTEMPTS

Date	Time	Comments	Participation		Meeting Place		
			Yes	No	Home	Hospital	Other

Recruiter, please check the following words that apply to the participant you called. Also write down any additional comments that the participant made or your feelings about your conversation.

- | | | |
|--|------------------------------------|--|
| <input type="checkbox"/> Enthusiastic | <input type="checkbox"/> Nervous | <input type="checkbox"/> Not sure if they want to participate |
| <input type="checkbox"/> Excited | <input type="checkbox"/> Hesitant | <input type="checkbox"/> Would like more information about the study |
| <input type="checkbox"/> Willing to help | <input type="checkbox"/> Angry | <input type="checkbox"/> Questions for staff about the study |
| <input type="checkbox"/> Pleasant | <input type="checkbox"/> Depressed | |

Additional Comments: _____

If Answering Machine: "I'm calling regarding a study at Mount Sinai and I will call back (specific time) or you may reach Senaka Peter at Mount Sinai by calling 1-866-223-2219 or 212 659-5406."

10/14/04

Reference: Role of the Recruiter

ID NUMBER: _____ REFERENCE DATE: _____

Please attempt to call subjects at least once between 9-11 a.m.; 1-5 p.m.; and 7-8 p.m. before determining whether you can reach them. Please attempt to contact this subject at least 5 times before _____ (return date)

PARTICIPANT RECRUITMENT FORM

[FORM FOR CASES, WOMEN WITH BREAST CANCER]

Hello, may I speak with _____
(WOMAN'S NAME)

(ONCE WOMAN IS ON THE PHONE):

Hello, my name is _____. I'm a breast cancer survivor (since _____ year of diagnosis, optional), involved in outreach for the Mount Sinai School of Medicine. You should have received a letter from Dr. _____ and the researchers here, as well as a postcard from me, telling you about an important study on breast cancer taking place at Mount Sinai Medical Center (and REFERRING HOSPITAL). Your doctor told us that you have indicated an interest in meeting with one of the interviewers for this study. If you have time, I would like to tell you about the study to help you decide whether or not you want to participate.

If **no**:

ASK FOR A BETTER TIME TO CALL BACK. TIME: _____

If **yes**:

I'll just take a minute to give you some background information:

Doctors and researchers are concerned, because breast cancer is becoming more common in women, and not much is known about what causes it or how to prevent it. Doctors at the Cancer Center are running a study to try to learn some of the causes of breast cancer. This study will compare women who have had breast cancer to women who have not, to learn why some get cancer and others do not. Before being diagnosed with this recent breast cancer, did you ever have breast cancer before, or any form of cancer other than basal cell or squamous cell skin cancer? **IF YES, FIND OUT WHAT TYPE OF CANCER, LET THEM KNOW THEY DO NOT QUALIFY FOR THE STUDY AND THANK THEM FOR THEIR TIME.**

IF THEY HAVE NOT HAD OTHER THAN THE ABOVE SKIN CANCERS, CONTINUE:

I would like to verify that you live in New York City six or more months out of the year. (If they ask why, explain that in order for our results to scientifically be valid, participants must reside in NYC six or more months out of the year.) **If no, let them know they do not qualify for the study and thank them for their time. If yes, then continue:**

I want to tell you right at the start that you do not have to agree to participate. If you do decide to participate, it will not cost you anything. People who agree to participate will be given a \$25 gift certificate from either Pathmark or Rite Aide as our way of thanking you for participating in our study. We will also provide a Metrocard for participants who need to travel in order to participate in this study. The privacy of everyone who participates will always be protected. No one other than the researchers will know who participated or who said what. Any information that is obtained will have a code number on it, not a name. You should also know that this is not a treatment study. If you decide to participate, it will not interfere with any treatment you may be having now or in the future. This study involves being interviewed by a woman who is a trained interviewer. She will be asking questions about diet, health history, and life style habits. She will take some measures of height, weight, and body size and will take a small sample of blood. These procedures will take about two hours. Do you have any questions for me so far?

(IF THEY HAVE QUESTIONS THAT YOU DO NOT KNOW THE ANSWER TO, TELL THEM AN INTERVIEWER WILL CALL BACK TO ANSWER THEIR QUESTIONS).

Do you think you would be interested in participating or at least learning more about the study before you decide? **(YES)**_____ **(NO)**_____

(IF NO, TRY TO FIND OUT WHY AND TRY TO CHANGE THEIR MIND. IF IT WOULD HELP, REFER TO Q&A NUMBER 5 REGARDING CANCER HISTORY. IF THEY STILL SAY NO, ASK): May I ask you just a few short questions about your medical history and socioeconomic background on the phone? (See Refuser Questionnaire)

(IF THEY AGREE TO PARTICIPATE, SAY):

That's great. I would like to schedule an appointment for you to meet with a female interviewer from the Cancer Center at one of our interview sites. **(Offer Mount Sinai to all women and, as an alternative, a hospital in their borough)** The interview can be conducted in **Manhattan** at either Mount Sinai Hospital, 98 St. & Fifth Ave. or St. Luke's Roosevelt Hospital, 59 St. & 9th Ave.; in **Queens** at Queens Hospital Center, 164th St. Jamaica, in **Brooklyn** at Kings County Hospital in Brooklyn (primarily Mondays and Fridays), or in the **Bronx** at either Montefiore Medical Center, East 210th St. or Albert Einstein College of Medicine on Eastchester Road (primarily Wednesdays or Fridays), whichever is more convenient for you. That's all there is to it. So, do you have any questions?

If the hospital sites are not acceptable, offer to have the interview done in their home.

I will be happy to set up an appointment for you. Will you be coming to Mount Sinai or do you prefer _____ hospital? What is a good time and day for you?

INTERVIEW LOCATION: _____
DAY INTERVIEW SCHEDULED: _____ DATE: _____ TIME: _____

I will tell let the Interviewers know you are interested in being in the study, and one of them will call to confirm the interview appointment. Keep in mind that even though you agreed to meet with the interviewer that you can change your mind at any time – even after you start the interview. But I am hoping that you will participate. Is this the best phone number at which to reach you?

(IF YES, WRITE DOWN THE PHONE NUMBER THAT YOU CALLED.
OR, IF THERE IS A BETTER NUMBER, WRITE IT DOWN HERE).

(____)____-____ Is there a good time of day to call you? TIME: _____.

Ok, so one of our Interviewers will be calling you soon to confirm your interview appointment on _____ (Date) at _____ (Time) and she'll be meeting you at:

Home: _____ Hospital: _____ Other: _____
If Hospital/Other, indicate building/room number: _____

If you should want to speak with someone before the Interviewer calls, let me give you the name and phone number of a contact person: (interviewer's) phone number: _____.
Thank you so much for your time, and for agreeing to be in this study.

Date Directions Sent _____

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Section: Recruitment Tools/Techniques

REFUSER QUESTIONNAIRE

1. What is your date of birth?

____/____/____
Month Day Year

2. Do you consider yourself to be of Latina or Hispanic origin?

- 1 ☐ Yes
2 ☐ No
9 ☐ DK /Refused

If **YES**: Do you consider yourself to be any of the following?
(Check all that apply)

- 1 ☐ Mexican/Mexican American/Chicano
2 ☐ Puerto Rican
3 ☐ Cuban
4 ☐ Caribbean or West Indian
5 ☐ Dominican
6 ☐ Other (please specify): _____

3. What is your race?

- 1 ☐ White
2 ☐ Black/African American
3 ☐ Black-Other
4 ☐ Black-West Indian / Caribbean
5 ☐ American Indian or Alaska Native
6 ☐ Asian Indian
7 ☐ Chinese
8 ☐ Filipino
9 ☐ Korean
10 ☐ Vietnamese
11 ☐ Other Asian
12 ☐ Native Hawaiian
13 ☐ Guamanian or Chamorro
14 ☐ Samoan
15 ☐ Other pacific Islander
16 ☐ Some other race

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Reference: Role of the Recruiter

4. What is the highest grade or year of school you have completed?

- 1 ☐ Less than 8th grade
2 ☐ 8th to 11th grade

- 3 ☐ High school graduate or equivalent (GED)
- 4 ☐ Technical or vocational school
- 5 ☐ Some college
- 6 ☐ College graduate
- 7 ☐ Post-graduate degree
- 9 ☐ DK/Refused

5. Do you have a mother, sister or daughter that has had breast cancer?

- 1 ☐ Yes
- 2 ☐ No
- 9 ☐ DK /Refused

6. Have you ever had a mammogram?

- 1 ☐ Yes
- 2 ☐ No
- 9 ☐ DK /Refused

7. During your lifetime, how many mammograms have you ever had?

____ (number) ☐ DK /Refused

8. What type of health insurance do you have?

- 1 ☐ Medicaid
- 2 ☐ Medicare
- 3 ☐ Employer-provided insurance (Oxford, Blue Cross/Blue Shield, HIP)
- 4 ☐ Pay for insurance out of pocket
- 5 ☐ I do not have health insurance
- 6 ☐ Other: _____
- 9 ☐ DK/Refused

9. How old were you when you had your first menstrual period?

____ (years) ☐ DK /Refused

10. How many SONS do you have? _____ (number of sons)

11. How many DAUGHTERS do you have? _____ (number of daughters)

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Reference: Role of the Recruiter

12. Have you gone through menopause, or the change of life?

- 1 ☐ Yes
- 2 ☐ No

9 ☐ DK /Refused

13. Have you ever taken birth control pills?

1 ☐ Yes
2 ☐ No
9 ☐ DK /Refused

14. Have you ever taken hormone replacement therapy?

1 ☐ Yes
2 ☐ No
9 ☐ DK /Refused

15. Do you currently smoke cigarettes?

1 ☐ Yes
2 ☐ No
9 ☐ DK /Refused

If no, did you ever smoke regularly?

1 ☐ Yes
2 ☐ No
9 ☐ DK /Refused

16. In the past year, how many times in a typical WEEK did you participate in moderate physical activity for at least 30 minutes per day?

___ (number of times per WEEK) ☐ DK /Refused

17. One year ago, how much did you weigh?

WEIGHT:

POUNDS.....1
KILOGRAMS.....2

Thank you for your time and helping the Mount Sinai School of Medicine.

10/14/2004
Reference: Role of the Recruiter

III.

ROLE OF THE INTERVIEWER

Overview

Interview Confirmation Script

Interviewer's Contact Sheet

Interviewer Training Outline

Division of Responsibilities

Travel Safety Tips

10/14/04

OVERVIEW OF INTERVIEWER ROLE

This section provides a brief overview of the tasks you are expected to perform as an interviewer. Each is discussed in detail in later sections of this manual.

1. After the successful completion of training, you will be given an assignment of cases and/or controls. These women will have already agreed to participate in the study and the recruiter will have set up an interview appointment. Your first job is **to send directions to the participant and confirm** the date, time and location for the interview.
2. If the interview is off-site, you will call-in upon arrival. You will then begin by obtaining a signed **consent form** for the interview and then administering the **main interview** and the **Food Frequency Questionnaire**. After this, you will introduce the **Early Life Experiences, IES, Behavior Change and How I Feel Scales** to the participant; while they finish these measures, you will **review** the main interview questionnaire and the FFQ for completeness and prepare to take the Anthropometry measurements.
3. When the FFQ has been completed, you will take the **Anthropometry measurements**.
4. The next task in the interview process will be to complete the **Blood Specimen Data Form** and then collect the blood specimen. (If this is not possible, a **DNA sample** will be collected). Material will be given to participant for their physician to do the blood draw, if they prefer. However, a DNA sample will still be taken in such cases.
5. You will give the participant the \$25 **gift certificate** and note the certificate number on the inside cover of the interview folder.
6. You will very briefly **introduce the 2nd and 3rd projects** to women meeting criteria for participation (discussed in later sections of the manual) and obtain consent for the telephone interview for Project 2, if appropriate.
7. You will **deliver** blood specimens to the GCRC lab and document in the **Lab Book**.
8. You will **record each contact** (via telephone or in person) with the participant from interview confirmation through completion in the "Interviewer Contacts" section of the **database**.
9. You will **enter all data** related to the interview process from confirmation of the interview appointment ("Participant Status" section) through completion of the interview ("Post-Interview Checklist" and "MHI") **within 24 hours** of the interview completion.
10. You will **edit** each questionnaire, reviewing all items for completeness and legibility prior to passing on for data entry
11. You will **report in person** to your supervisor for regularly scheduled conferences.
12. All work will be reviewed for accuracy and completeness. **Interviews will be validated** periodically by re-contacting respondents.

10/14/04

Reference: Role of the Interviewer

Interview Confirmation Script

Hello, Ms. _____; my name is _____ and I work with Dr. Ambrosone at Mount Sinai School of Medicine. _____ (Recruiter) told me she spoke with you about our breast cancer study and that you agreed to participate, which is great.

If you were originally scheduled for the interview:

I'm just calling to confirm our appointment on (Day) _____ (Date) _____ at (Time) _____. Do you have a moment to talk?

If you were not originally scheduled for the interview:

I know _____ (Recruiter) said _____ (Interviewer) would be doing the interview with you. However, _____ (Interviewer) is not able to meet with you on that day so I will be doing the interview, instead. So I just wanted to introduce myself and confirm the appointment, if you have a moment to talk?

If no, ask for a better time to contact them and write it here _____.

If yes: I'd like to take a moment to tell you a bit more about the study.

You may remember that _____ (recruiter) told you that the study will look for things that may cause breast cancer by comparing women who have had breast cancer to women who have not. Understanding things that may cause breast cancer will help us teach women how to change their lifestyle habits to help them stay well. Do you have any questions about the interview?

If needed: The interview will include questions about your work, family, health, and diet history. You will also be asked to give a small blood sample at the time of your scheduled appointment and measurements will be taken, such as your height and weight. The entire process will take only about 2 hours. As an appreciation for your time and effort, I will be bringing the \$25 gift certificate for (Pathmark or Rite Aid) with me.

Ok, then, I'd like to confirm that we're meeting at:

Place of interview: _____

Address of location: _____

Brief directions to location (if needed): _____

I just have one suggestion for you in terms of the interview: **if you could wear comfortable, light, loose-fitting clothing, such as slacks and a short-sleeve shirt and socks or knee highs instead of stockings, it would make it much easier to take the body measurements, ok?**

Thank you Ms. _____, for taking time to talk with me today. I look forward to seeing you on (Day) _____ (Date) _____ (Time) _____ at (Location) _____. If you have a pen handy, I can give you my phone number in case you have any questions beforehand or need to change your appointment; ok, ready? My name is _____ and you can reach me at Mount Sinai at 212 659- _____ or my cell phone number, which is: _____.

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Reference: Role of the Interviewer

Participant ID: _____
Reference Date: _____

Interviewer ID : _____

INTERVIEWER'S CONTACT SHEET

PARTICIPANT'S NAME _____

PHONE NUMBER _____

1. DATE: ____/____/____ RESULT: _____
TIME: _____

STATUS: _____

2. DATE: ____/____/____ RESULT: _____
TIME: _____

STATUS: _____

3. DATE: ____/____/____ RESULT: _____
TIME: _____

STATUS: _____

4. DATE: ____/____/____ RESULT: _____
TIME: _____

STATUS: _____

5. DATE: ____/____/____ RESULT: _____
TIME: _____

STATUS: _____

INTERVIEW CONFIRMED: _____ RESCHEDULED DATE/TIME: _____

DIRECTIONS SENT _____

INTERVIEW REFUSED: _____ REASON: _____

DATE INTERVIEW HELD: _____

10/14/04

Reference: Role of the Interviewer

INTERVIEWER TRAINING OUTLINE

These are case-control studies of women with breast cancer (cases), women similar to cases with regard to age and place of residence, but who do not have cancer (controls), and the adult healthy daughters of both the cases and controls.

These studies are designed to examine the genetic and environmental risk factors, the interest in genetic counseling and testing for BRCA testing, and the immunologic parameters of African American women recently diagnosed with breast cancer.

WHY INTERVIEW SUBJECTS IN PERSON?

1. More people will agree to answer questions when asked by another person, than will agree to respond to a questionnaire sent in the mail.
2. People are more likely to choose a specific response to a question if they are asked to respond by an interviewer, as opposed to saying, 'I don't know'. Interviewers can help subjects think through a question to provide an answer.
3. Interviewers can help clarify questions that the respondent doesn't understand.
4. Interviewers can observe respondents, noting information that might not be easily ascertained in a questionnaire, like a person's dress or grooming, surroundings, and her ability to read, write, or speak English.

INTERVIEWER ROLE

Goal: *The interviewer's role is to make sure that each question means the same thing to each respondent.*

The interviewer's presence should affect neither a respondent's perception of a question nor the answer given. The interviewer must always remain neutral.

MANDATORY INTERVIEWER CHARACTERISTICS

- Neat, well groomed
- Well-spoken
- Relaxed (but professional)
- Friendly (but not clingy)

LEARNING THE QUESTIONNAIRE

- Study each question carefully
- Practice reading the questions aloud
- Practice the questionnaire first on people you know well

QUESTIONNAIRE MASTERY

- No errors when reading questions

- Smooth, natural delivery, consistent across interviews

RECORDING RESPONSES

1. Record the answers to open-ended questions exactly as they are given. Do not simplify, interpret or correct grammar in responses.
2. Write comments that explain response when ever possible (e.g., a respondent appears to be embarrassed about answering, a respondent seemed offended by the question).
3. Probe for responses by asking for more information or by remaining silent and letting the respondent clarify his or her response spontaneously. **PROBES MUST BE COMPLETELY NEUTRAL.**

10/14/04

Reference: Role of the Interviewer

Division of Core A Responsibilities
(October 2004)

Lina Jandorf:

- Monitoring Interviewers' comp time status.
- Tracking time for questionnaire and self-reports completion.
- Coordinating interview scheduling among interviewers when scheduling conflicts exist.
- Assigning Recruiters/Interviewers.
- Coordination between Core A and Center Grant Projects.
- Interviewing and training recruiters.
- Interviewing and training new Interviewers.

Rose Bialecki:

- Developing agenda and minutes for weekly Core A Meeting.
- Producing Recruiter Newsletter
- Telephone screening, interviewing and training recruiters and tracking processing of volunteer paperwork.
- On-going updating of Interviewer/Recruiter Manuals.
- Reserve SLR and Beth Israel interview space.
- Develop recruiter postcards
- Maintain supply of direction sheets to hospitals
- Develop and print Tri-State Thank You cards

Sherly Jacob:

- Reserve KC and Queens Hospital interview space.
- Maintain supplies in KC and Queens Hospital.
- Maintain clerical supplies, including gift certificates, postage, metro cards, forms, etc.
- Update interviewer contact cards.
- Update Show Cards
- Maintain supply of Project 1 paperwork (excluding consents, HIPAA, and direction sheets)

Melissa Solis:

- Reserve Weiler and Moses interview space.
- Maintain supplies in Weiler/Moses.
- Notify GCRC and lab weekly re interviews.
- Maintain blood draw supplies, including FedEx.
- Weekly reports for Core A meeting.
- Maintain supply of consents, HIPAA forms, etc.

Nadine Robinson:

- Maintain Anthropometry supplies.
- Maintain Klingenstein supplies
- Order FFQ
- Alert Senaka Peter when Project 1 questionnaires need to be ordered
- Maintain supply of Project 2 paperwork
- Maintain supply of Project 3 paperwork

All Interviewers:

- Complete Project 1 Interviews.
- Reserve rooms at Klingenstein.
- Send out recruiter mailings.
- Maintain weekly contact with Recruiters.
- Attend Recruiter/Interviewer Meetings.
- Maintain database on a daily basis.
- Re-schedule interviews.
- Train new Interviewers
- On-site recruitment at Kings County and other clinic sites.
- Project 2 and 3 Interviews

10/14/04

Reference: Role of the interviewer

TRAVEL SAFETY TIPS

BODY LANGUAGE

- Look Confident and sure about your destination. Take a copy of confirmed directions with you.
- Wear clothing that blends in well.
- If you must wear jewelry, moderation is the rule.
- Wear sneakers or comfortable shoes.
- Walk confident and make good eye contact.

AUTOMATED TELLERS

- Use only in well-lit areas.
- Be aware of what's going on around you.

SUBWAY SAFETY

- Travel during peak hours, whenever possible.
- Sit in subway car where motorman is located.
- Wait for trains near token booth.

TRAVELING

- Confirm your destination ahead of time and make sure a supervisor has a copy of your travel plans.
- Call when you arrive at interview location and before you leave. It's always a good idea for another party to know your time schedule.
- Use cellular phone to call for assistance at any time.
- Always remember that no matter what the situation:
 - REMAIN CALM
 - USE COMMON SENSE
 - IF IT DOESN'T:
 - Feel right
 - Look right
 - Sound right-**DON'T DO IT!!**

10/14/04

Reference:Role of the Interviewer

IV.

Interview Process

Mount Sinai Hospital

St. Luke's Roosevelt Hospital

Beth Israel Hospital

Kings County Hospital

Montefiore Medical Centers

Queens Hospitals

In-Home

All Interviews

HIPAA & Consent Procedures

Flow of Interviews

INTERVIEWS AT MOUNT SINAI HOSPITAL

Scheduling Blood Processing at the GCRC

After confirming the interview date, time and location, the GCRC will be notified by Melissa Solis via e-mail (Schedule-CRC) of the scheduled interview and the approximate time for the blood draw and/or blood processing. All blood draws performed at the GCRC will be done by GCRC staff nurse practitioners. If an interview is cancelled or no blood specimen obtained, Interviewer will notify both Shen and Rui at x85483, as well as the GCRC at x46041, not to expect a blood specimen. Melissa e-mails the blood draw schedule on Thursday for the following week (Monday through Saturday). If an interview is scheduled with less than a week's notice, the interviewer will contact GCRC and Shen and Rui to inform them of the extra specimen. When in doubt consult Melissa.

Scheduling the Interview at the Klingenstein Pavilion

A sign-up calendar is maintained on the J-Drive in the folder labeled "KPCal". After confirmation of the appointment, reserve a room by placing the interviewer's name in the time slots needed. The calendar is a Word document and must be SAVED every time a change is made. If the room in KP is no longer needed (reschedules or no shows) delete the interviewers name from the calendar. The participant will be met in the lobby and accompanied to Suite 5, first floor. See "Hospital Info." Section for details.

INTERVIEWS AT ST. LUKE'S ROOSEVELT HOSPITAL

After confirming the interview date, time and location, Rose Bialecki should be notified that a room is needed at SLR. She will contact John Oliver (212 523-7131) and confirm that a room is available for the interview to take place. Directions will be sent to the participant, if needed. Blood draw and processing will follow the same procedure as for Mount Sinai. See "Hospital Info." Section for details.

INTERVIEWS AT BETH ISRAEL HOSPITAL

After confirming the interview date, time and location, Rose Bialecki should be notified that a room is needed at BI. She will contact Tanya (212-844-8294) and confirm that a room is available for the interview to take place. Directions will be sent to the participant, if needed. Blood draw and processing will follow the same procedure as for Mount Sinai. See "Hospital Info." Section for details.

INTERVIEWS AT KINGS COUNTY HOSPITAL

At a minimum, one Interviewer will be assigned to Kings County to both recruit and interview. Other Brooklyn patients can also be scheduled by additional recruiters at Kings County; after confirmation, Interviewer will advise Sherly Jacob who will arrange for interview space with Deborah Bristol (718-245-4779/4737; DFYB1963@aol.com). Blood specimens will be returned

to the GCRC for processing, either by the Interviewer or via Federal Express, with the same procedures as Mount Sinai. See "Hospital Info." Section for details.

INTERVIEWS AT MONTEFIORE MEDICAL CENTERS

Nursing staff, including Una Hopkins at Weiler (718 405-8522) and Cathy Sarta at Moses (718 920-2059), and Interviewers will serve as Recruiters and schedule the appointments which will take place in an office at the hospitals. Other Bronx patients can also be scheduled by additional recruiters at the 2 Bronx sites; after confirmation, Interviewer will advise Melissa Solis who will arrange for interview space. Blood specimens will be returned to the GCRC for processing, either by the Interviewer or via Federal Express, with the same procedures as Mount Sinai. See "Hospital Info." Section for details.

INTERVIEWS AT A QUEENS HOSPITAL

After confirming the interview date, time and location, Sherly Jacob should be notified that a room is needed. She will contact Sharyn Parness at Queens Hospital Center (718 883-3751; 718 223-1908 PIN 24790) or Jennifer Goh at New York Hospital Queens (718-670-1185) and confirm that a room is available for the interview to take place. Directions will be sent to the participant, if needed. Blood draw and processing will follow the same procedure as for Mount Sinai. See "Hospital Info." Section for details.

IN – HOME INTERVIEWS

Introduction at the Door

Once you have located the participant's home (using the Participant Recruitment Form and street map) you are ready to contact her. (Should you feel uncomfortable in the neighborhood and/or interview setting, advise the participant that you are unable to complete the interview and reschedule at a time when you can be accompanied by another interviewer). Upon arrival, activate your cell phone and notify the office you are at the participant's home. Although in most cases you have already introduced yourself and the study during the telephone call to confirm the appointment, you should be prepared to repeat all or part of that introduction if necessary. Always have your **ID** badge visible and have a copy of the brochure for reference. Be prepared to answer any questions asked briefly, to the point, and accurately.

Setting of the Interview

Find a comfortable, well-lighted and private place in the home. Ideally, this would include a table and two chairs so you can be face to face during the interview. However, keep in mind that you must accommodate to her home, and family situation. You may suggest an ideal interview setting but you must comply with her wishes (e.g., wants to have spouse or daughter participate, has no private space in home, etc). You may suggest that there are some parts of the interview which she may prefer to keep private, if possible.

ALL INTERVIEWS

HIPAA & Consent Procedures

HIPAA is the acronym for the Health Insurance Portability and Accountability Act. It was passed in 1996 and was made effective April 14, 2003. These federal regulations are intended to ensure patients' privacy requirements. Because of this change in policy, participants will now receive a HIPPA notification form that they will need to sign stating that they received it. In addition, participants will be asked to sign a consent form and a HIPPA authorization form for this study.

Cases:

All cases should receive HIPAA notification, HIPAA authorization, and informed consent from the hospital, which referred them, regardless of the location of the interview.

1. Ask participant if they have received the HIPAA notification form from their referring hospital.
 - a. If yes, go to #3
 - b. If no, go to #2
2. Give participant HIPAA notification form from their referring hospital and ask them to sign that they received it.
3. Ask participant to read over and sign the HIPAA authorization form from their referring hospital.
4. Go over informed consent from their referring hospital and ask them to sign it **ONLY** after you are sure they understand the consent completely.

**** If the case from a hospital other than Mount Sinai needs to have blood drawn at Mount Sinai by GCRC, the interviewer needs to go through steps 1 – 4 again with Mount Sinai HIPAA notification, Mount Sinai HIPAA authorization, and Mount Sinai informed consent. In addition, GCRC needs a copy of the signed Mount Sinai consent form every time they draw blood for this study.**

Controls:

All controls should receive HIPAA notification, HIPAA authorization, and informed consent from the hospital where the interview is taking place. If the interview is conducted at the participant's home, Mount Sinai HIPAA notification, HIPAA authorization, and informed consent should be used.

1. Ask participant if they have received the HIPAA notification form from the site where the interview is taking place.
 - a. If yes, go to #3
 - b. If no, go to #2
2. Give participant HIPAA notification form from the site where the interview is taking place and ask them to sign that they received it.

3. Ask participant to read over and sign the HIPAA authorization form from site where the interview is taking place.
4. Go over informed consent from the site where the interview is taking place and ask them to sign it **ONLY** after you are sure they understand the consent completely.

Obtaining Informed Consent

After you have gained cooperation and before you begin any data collection activities, you will need to obtain the participant's informed consent. Informed consent involves telling the participant exactly what her participation entails as well as her rights as a research participant. If participant indicates an inability to understand the consent process, either due to mental impairment or language barrier, the interview cannot proceed because the participant cannot consent in an informed manner. Likewise, if the participant exhibits an inability to complete the interview for any reason, including physical discomfort or symptoms, the interview can be abbreviated and, if possible, completed at another time.

The consent form provides the following information:

- A brief description of the study;
- A list of the study components for which consent is being sought;
- Information on the voluntary nature of participation;
- A description of the steps the researchers will take to maintain confidentiality and assurances that the data will be used for research purposes only; and
- The name and number of study researchers to call if there are any questions about the individual's rights as a research participant.

Remember it is critical that each consent form be presented to the participant prior to undertaking the specific tasks stated in each form and that the appropriate consent form be used for each participating institution, i.e., Mount Sinai, St. Luke's Roosevelt, etc. After the participant signs and dates the consent form and initials each page, give a copy of the completed form to her. **All controls will be consented under the consent of the hospital where the interview takes place. If it is done in the home, the Mount Sinai consent will be used. Cases will be consented under the consent of the referring hospital.**

The goal for cases and controls is to administer all the study components in one visit, in the following order:

- HIPAA notification and authorization;
- Consent Form;
- Main Questionnaire;
- Food Frequency Questionnaire
- Behavior Change, Early Life Experiences, IES, How I Feel Scale (all self-administered);
- Anthropometry measures;
- Blood Draw;
- Introduction of Projects 2 and 3
- Consent for Project 2 Telephone Interview, if applicable.

If the participant cannot complete the interview at one appointment due to time constraints, take the Anthropometry measures and blood draw at the first interview; complete the remainder of the questionnaires at the next one.

FLOW OF INTERVIEWS

- Administer **HIPAA notification and authorization, consent** followed by **main questionnaire**. Show cards help the questionnaire go by quicker.
- Help the participant get started with the **FFQ**. You can sit next to her and ask her the first few items in order to orient her to the form and also to get a sense of her reading ability. If you feel she is not understanding the FFQ or she can't read well, then please ask her the questions. Otherwise, get her started and then let her finish it up. After she gets done with the FFQ, look over it to be sure she filled everything out correctly, and hand her the **Behavior Change Questionnaire, Early Life Experiences, Impact of Events, How I Feel Scale**(assuming she can read and is receptive).
- While she is doing these final questionnaires, please do the following:
 1. **Code the "activities"** in the physical activity section.
 2. **Review questionnaire** and check answers to make sure everything is filled out properly. (It is important to do this while you are still with the participant in case you realize that a question was not asked, or section was skipped so you can ask her any remaining things!) While reviewing, **check eligibility** for Projects 2 and 3.
 3. **Set up** for anthropometry and blood draw.
- Perform **Anthropometry Measurements**
- Before the blood draw, have participant fill out the **Self--administered Specimen Checklist**. (This questionnaire deals with what she ate, drank or took in the past 2 days. This is so we know what to expect in the blood samples).
- Perform **Blood Draw**
- Present **Projects 2 and 3** for eligible participants
- Administer Project 2 **Telephone Interview Consent** for all eligible African American cases.

10/14/04

Reference: Interview Process

V.

QUESTIONNAIRE ADMINISTRATION

Interview Topic Outline

Questionnaire Reminders

Averting Refusals

Interviewer Questions and Answers

Emotional Reactivity

INTERVIEW TOPIC OUTLINE

- **DEMOGRAPHICS:** Personal, demographic information.
- **FAMILY HEALTH HISTORY:** Cancer history of all immediate blood relatives: parents, siblings, children.
- **PRENATAL EXPOSURES:** Few questions on mother's pregnancy.
- **MENSTRUAL HISTORY:** Reproductive and medical history including childbirth, breastfeeding practices for each child, oral contraceptives and Hormone Replacement Therapy (HRT).
- **MEDICAL HISTORY:** A few questions on specific diseases, medications and mammography screening.
- **SMOKING HISTORY:** Few questions on cigarette smoking and passive smoking exposure.
- **DEVELOPMENTAL HISTORY/ PHYSICAL ACTIVITY:** Height and weight, physical activity patterns including history and job related physical activities.
- **STRESSOR EVENTS:** Lifetime history of stressful events, such as unemployment, death, moving etc.
- **LIFESTYLE:** Questions about living environment, alcohol consumption, household income.
- **BEHAVIOR CHANGE:** Change in behaviors since reference date.
- **SENSITIVE QUESTIONS:** Regarding childhood.
- **EMOTIONAL STATUS:** Present and cancer related.

10/14/04

Reference: Questionnaire Admin.

Questionnaire Reminders

Questionnaire – See QxQ for question by question directions.

Rounding: Round up if more than $\frac{1}{2}$ (See QxQ).

Probe for specific responses, if participant unsure. Ranges are not appropriate.

Check only one response unless indicated otherwise.

Check questionnaire for missing page numbers.

Check questionnaire for consistency in response, i.e., respondent has 3 children but only two names are listed.

Check questionnaire for accuracy, i.e., 20 years exercising started at age 17; if the respondent is now 34, that's incorrect.

Self-Reports

FFQ: make sure all bubbles are completely filled out in pencil.

Reference date must be included; refers to one year prior to the questionnaire reference date.

Never or less than 1x/month does not need an amount.

Blood Specimen Checklist: remove last page with a control. Complete Interviewer information.

Behavior Change: "other" should not be checked for no change.

All: Review self-reports for missing or conflicting responses and clarify answers.

Self-reports can be done over the phone, if the respondent has not returned via mail.

If returned by mail and today's date is missing, use the date returned, less 2 days.

10/14/04

Reference: Questionnaire Admin.

AVERTING REFUSALS

1. **BE EMPATHETIC WITH YOUR SUBJECT.** How would you feel if someone you didn't know wanted to interview you? What would make you feel at ease with a stranger who wants both your time and a lot of personal information?
 - **BE SENSITIVE** to the participant's perspective on life. Get a sense of what she finds is important, pay attention to her living situation and her limitations.
 - **ESTABLISH RAPPORT.** Start off on the right foot. Offer a compliment about her house/apartment. Be careful not to appear condescending or say anything that may influence her answers during the interview. Treat her with the respect she deserves.
 - **BODY LANGUAGE IS IMPORTANT.** Present a calm, professional, pleasant demeanor. Your sense of confidence and competence will be communicated by your positive attitude.
 - **ASK "YES" ANSWER QUESTIONS.** If you get to a stage at the introduction and think a refusal is pending, ask questions that will elicit a "Yes" response. If she starts agreeing with you, it will be harder for her to refuse later. For example:

"Breast cancer is an important health issue facing women today, don't you agree?"

"To improve the health care system we all need to help out, don't you think?"
 - **FOCUS ON THE PARTICIPANT.** Don't be self-conscious. Use eye contact (when in-person) to draw out her concerns. Be a good listener.
 - **IGNORE NEGATIVE COMMENTS.** This is not as hard to do as you may think. Don't take negative comments personally; they are not directed at you. If she says something negative, say "uh huh" or nothing, and wait. The pause will let her know she has said something inappropriate.
 - **START THE STUDY TASKS QUICKLY.** Once you begin conducting the various activities, the participant will see that her fears are unfounded.
2. **STOP BEFORE THE PARTICIPANT REFUSES.** If you still find that you cannot convince a woman to participate in the study, **leave the door open for someone else to make a further attempt.** Try to leave on a friendly note. If the situation allows, ask her to think about the study and suggest something like:

"Why don't you think about it for a few days. My supervisor or another study interviewer will contact you at another time. This study has great value."

Exit gracefully and leave the person receptive to the efforts of a different interviewer.

10/14/04

Reference: Questionnaire Admin.

INTERVIEWER QUESTIONS/ANSWERS

1. I don't have time/interview is too long:

I know that this takes a bit of time but there are still many things that health educators and researchers don't know about women and breast cancer. This information is important in helping us to better address the needs of local communities. In order to complete the interview, we can work around your schedule. Your help is so important to us because the information you give us about your lifestyle and family and medical history could help us to reduce the number of people who develop and die from breast cancer.

2. I don't know how this information is going to be used/don't know who will see my answers:

All the information you provide will be confidential. Your interview answers will not be marked with your name, but with a code number. Any personal information we obtain from you will be separated from your interview answers. Your help is so important to us because the information you give us about your lifestyle and family and medical history could help us to reduce the number of people who develop and die from breast cancer.

3. Why are you asking questions about my parents, children and other relatives?

There are differences in the incidence of breast cancer between ethnic groups, e.g., Hispanic women have less breast cancer than African American and White women, so researchers are looking at both genes and the environment to help understand why these differences occur.

4. I'm receiving chemotherapy right now/just finished treatment; can I still participate?

This is not a treatment study and your involvement will not interfere with any treatment you may be undergoing/have recently completed. The study consists of a one-time interview, at which we would take a small blood sample, as well as body measurements. That's all there is to it.

5. Why do you need to take my blood; what will you do with it?

The purpose of the study is to try to understand why some women get breast cancer and others do not. Not everyone with similar habits or characteristics will get breast cancer. This may be because of individual differences in how our bodies make the substances needed to keep everything working right. Just as people differ from one another in how they look, they also differ in what goes on inside their bodies and in how their bodies respond to things they eat, drink and smoke, as well as medications they take. In this study, we will compare some of these factors between women with breast cancer and women without.

6. Why are you asking about whether I was breastfed or whether I breastfed my children?

Breastfeeding has been shown to provide protection against certain autoimmune diseases, such as diabetes; researchers are interested in any differences in women who have had breast cancer and those who have not so this is one area they are looking at.

7. Why are you asking about age at menstruation/age of first pregnancy?

Some research has shown a relationship between age of menstruation (age of first pregnancy) and frequency of breast cancer so this is one area researchers are interested in.

8. Why are you asking about oral contraceptives and HRT?

Estrogen has been linked to some types of breast cancer; researchers are looking at the amount of estrogen a woman has been exposed to during her lifetime to see if that is related to whether or not women develop breast cancer.

9. Why are you interested in how much aspirin, etc. I take?

Aspirin has been shown to be protective in certain circumstances against heart disease but can cause other physical problems, such as stomach irritation. Researchers are interested in whether aspirin or other over the counter medications may be related to differences in who develops breast cancer and who doesn't.

10. Why do you want to know if I dye my hair?

Researchers are looking at whether hair dye is related to who gets or who doesn't get breast cancer.

11. Why are you asking about the people I lived with when I was growing up?

Researchers are interested in whether our environment, including things like household conditions such as the size of the family, is related to who gets or who doesn't get breast cancer.

12. Why are you interested in my height and weight growing up?

Researchers are looking at ways in which our bodies change over time and whether those changes are related to those who get and those who don't get breast cancer.

13. Why are you asking about the jobs I've had/amount of physical activity?

Some studies have shown exercise to be related to less risk of breast cancer; researchers are interested in looking at women's lifetime physical activity to see if there is a difference between women who have developed breast cancer and those who have not.

14. Why are you asking about my childhood experiences (abuse, trauma, poverty)?

These are standardized questionnaires. Researchers don't really know much about how our early experiences may or may not affect our adult health; it is hoped these questions will help them start to understand whether or not this is the case.

15. I had skin cancer but I don't know which kind I had.

Basal cell or squamous cell carcinoma rarely metastasize in contrast to melanoma which may result in metastasis.

Patient refuses a second time

Thank you for listening. Please take my number or card in case you change your mind. Would you mind answering just a few questions? Proceed to Refuser Questionnaire.

10/14/04

Reference: Questionnaire Admin.

Emotional Reactivity

During a Project 1 Interview

It is possible that the experience of undergoing an interview may reveal some negative feelings related to having breast cancer or some other life event or circumstance. Interviewers should observe respondents carefully throughout the interview for both verbal and non-verbal cues that distress is being experienced, and to respond appropriately. Depending on the amount and nature of the distress, the Interviewer may:

- suggest a short break;
- offer to postpone completion of the interview to another day;
- ask if assistance from a family member is wanted;
- contact Lina Jandorf for assistance.

In reviewing the "How I Feel " Scale, if more than one question is answered with the indicated response, or if depression (question 9) or emotional instability (question 18) are answered in the affirmative, the Interviewer should ascertain whether the participant is currently seeing a therapist. If not, let them know that Lina Jandorf may be contacting them post-interview, as a normal follow-up. If respondent does not presently have a therapist but is interested in locating someone, the following resources can be offered:

Anne Fatone, Ph.D. (clinical psychologist): 212-860-8500
Ann Webster, Ph.D. (clinical psychologist): 212 799-5449
Jane Karp, M.D. (psychiatrist): 212 772-0025
Robin Zarel, CSW (social worker) 212 247-4206
Mount Sinai Breast Health Resource Center (cases only): 212 987-3063
(services are free at the Resource Center only).

After the interview, Interviewers complete the Mental Health Index Summary section of the Post-Interview Checklist field in the database. If responses indicate the need for follow-up and the respondent does not have a therapist, the Mental Health Index Summary Sheet will be completed and given to Lina Jandorf for follow-up within 24 hours of interview. If follow-up is not indicated, data will be entered indicating depressive symptomatology criteria was not met and respondent does not need to be contacted.

10/14/04

Reference: Questionnaire Admin.

Interview Date: _____

Location: _____

**Mental Health Inventory Summary Sheet
(How I Feel Scale)**

<u>Question</u>	<u>Response</u>	<u>Yes*</u>	<u>No</u>
HIFS2	1	___	___
HIFS4	6	___	___
HIFS9	1 or 2	___	___
HIFS16	1 or 2	___	___
HIFS18	6	___	___

***If yes response to two or more, or yes response to either 9 or 18, MIH Summary Sheet given to:**

L. Jandorf _____ Date: _____

Place ID label here:

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Reference: Questionnaire Admin.

VI.

Blood Draw

Phlebotomy Training Protocol

Practice Log Sheet

Interviewer Tracking

Introduction to Blood Draw

Biosafety

Blood Draw Protocols

Blood Draw Procedures

Unusual Occurrences

Incident/Emergency Report Form

Needlestick/Sharps Injury Procedures

Blood Paperwork

Phlebotomy Training Protocol

1. Trainee must attend a 3-hour vascular module sponsored by the MSMC Nursing Department.
2. Once the 3-hour vascular module has been completed, the trainee is required to successfully complete 6 blood draws in a controlled setting, before entering the field. The subjects of the blood draw should sign the Phlebotomy Practice Log Sheet.

Note: the more practice the more confident the trainee will become, therefore, it is suggested that the trainee compete more than the 6 required blood draws.

3. Once the trainee has successfully completed the 6 required blood draws, the Phlebotomy Practice Log Sheet will be kept on file.
4. Efforts should be made to perform the blood draws on an ethnically-diverse group of women. Reflecting the population of the study, this should include at least two African American women.

Reference: Blood Draw

PHLEBOTOMY PRACTICE LOG SHEET

Interviewer Name: _____

Phlebotomy Training Date: _____ *

Name of Volunteer	Date of Blood Draw	Volunteer's Signature

Supervisor's Signature: _____

*6 Blood Draws must be completed as part of Interviewer Training

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Reference: Blood Draw

Interviewer Tracking

Name of Interviewer: _____

Phlebotomy Training: _____
(Contact: Sylvia McBirney x47050)

Phlebotomy Practice Complete: _____

CPR Training: _____
(Contact: Sylvia McBirney)

Anthropometry Training: _____
(Contact: Julie Britton, Ph.D., x45488)

GCRC Orientation: _____

10/14/04
Reference: Blood Draw

Introduction to Blood Draw

To gain cooperation, you must be prepared to address the subject's concerns effectively. Therefore, be sure you are familiar with the following information about the procedures to be used for the study:

- You must be able to describe the tubes that are to be drawn and summarize the testing that will be done by the researchers at MSSM. Stress that this is not a multi-stick procedure; all three tubes will be drawn with one venipuncture.
- The blood draw will only cause minimal discomfort. The body manufactures blood daily and this small volume of blood (24 ml) will be completely replaced within 24 hours.
- The supplies used for the blood draw are completely sterile, and they are used only once. After use they are destroyed. There is absolutely no possibility of the subject being infected by any blood-borne disease, such as hepatitis or AIDS, as a result of participating in the Tri-State Women's Circle of Health Breast Cancer Study Project.

Gaining the cooperation of the subject will be easier if the atmosphere is pleasant and you make the subject feel comfortable. Below is a list of suggestions for creating a pleasant atmosphere.

- Maintain a clean and uncluttered work surface. This is especially important because of today's concern with blood-borne infectious diseases, such as hepatitis and AIDS.
- Be aware of your body language: a positive body image inspires confidence. Maintain a tidy appearance, erect posture, and a pleasant expression.
- Speak face-to-face with the subject and maintain eye contact. Staring at other areas in the room may cause the subject some uneasiness since it implies that she is not important and you are not interested in performing the blood draw.
- Avoid nervous behaviors, such as squirming and tapping, which can distract you and the subject. The subject may begin to feel nervous, hurried, and anxious as a result of such behaviors.
- Avoid distractions such as TV, radio, or food cooking on the stove. At times you may need to request that you move the blood draw into a room which would give you complete privacy.

10/14/04

Reference: Blood Draw

BIOSAFETY

Overview

Standard laboratory precautions to minimize the spread of infectious disease must be followed. These recommendations have been developed and compiled by **CDC**.

- All blood samples are considered to be potentially infectious and must be handled with extreme care.
- Extraordinary care must be taken to avoid accidental needle sticks or cuts from broken glass. This can occur as a result of careless technique and improper disposal of used needles and blood drawing equipment. Extraordinary care must be taken to dispose of needles immediately after use in a puncture proof box.
- Gloves must be worn during venipuncture and at all times when handling the blood samples and contaminated material. Cuts or abrasions should be protected under the gloves.
- Hands should be washed with soap and water or antibacterial handwipe before and after each blood draw. A new pair of gloves should be worn for each subject.
- Work surfaces should be covered with Chuks at all times.
- Blood spills should be cleaned promptly with absorbent material, using a 1:10 dilution of bleach and water or antibacterial handwipe.
- All needles or blood collection sets are sterile and are to be used only once.
- All needles or blood collection sets must be disposed of immediately after use, in a puncture-proof sharps container clearly marked "Biohazard." Needles are never to be re-capped, bent, or cut.
- Broken glass should be disposed of in the puncture proof sharps box.
- Never leave any material at a drawing site.
- All contaminated material should be disposed of in a sturdy closeable bag clearly marked **BIOHAZARD**.
- Only authorized personnel are to handle the supplies, equipment and samples.
- Eating, drinking or smoking is prohibited in areas where blood is processed or stored.

10/14/04

Reference: Blood Draw

PROTOCOL FOR COLLECTION OF BLOOD SAMPLES

1. After anthropometry, have participant complete Specimen Collection Checklist and then collect blood (24 ml.):

1-10ml. Red-top tube for serum and blood clots.

1- 4ml. Purple-top tube (EDTA) for DNA extraction.

1-10ml. Green-top tube (sodium heparin additive) for plasma and buffy coat.

Blood should be collected in the following order: 1 red, 1 purple, 1 green.

2. Specimens are inserted into either a bio-hazard bag (on-site interview) or styrofoam transport (off-site interview). Protect specimens from light.
3. Blood specimens will be taken to the General Clinical Research Center (GCRC) at 1184 Fifth Avenue, 2nd floor, for initial processing by Core C. The purple vial will be left in biohazard bag, with a copy of the Specimen Collection Record, in a basket in room 296 of the Molecular Biology Core laboratory, 1184 Fifth Ave. The red and green vials will be taken to the GCRC along with a copy of the Specimen Collection Record, one sheet of barcode labels and the GCRC Physician Order Sheet. After 5:00 PM weekdays or on weekends, all tubes will be taken to the GCRC, with both copies of the Specimen Collection Record. The date and time of specimen delivery will be recorded in the GCRC Log Book.
4. There may be participants who prefer to have blood drawn by their own physician. In order to accommodate this request, the following process will be followed:
 - Label the Self-administered Specimen Checklist.
 - Label the empty vials before placing them in the Styrofoam box, then in the cardboard box and, finally, in the Diagnostic Specimen Envelope.
 - Complete the recipient part of the FedEx USA Airbill as follows:
 - Mount Sinai School of Medicine, 1425 Madison Ave., Suite 1670, New York, N.Y. 10029; Attention: Senaka Peter-Center Grant; check recipient for payment and put our account number: 2519-4716-3; check 4a (Priority Overnight).
 - Attach the filled out FedEx USA Airbill to the Diagnostic Specimen Envelope.
 - Place the Self-administered Specimen Checklist and the Instructions for Physicians in the Diagnostic Specimen Envelope.
 - Give this material to the participant for them to bring to their physician. Remind participant to complete **Self-administered Specimen Checklist** prior to the blood draw. Let participant know that **blood cannot be drawn on a Friday** because blood processing may not be available until Monday. So their physician can draw their blood from Monday through Thursday.

- **The Interviewer is responsible for following up with the participant and/or her physician and notifying Lab personnel when to expect the specimen shipment.**
5. **For Mount Sinai Participants ONLY.** There may be participants interviewed at Mount Sinai who prefer to have their blood drawn by the GCRC. If an Interviewer cannot obtain a blood sample or if the participant knows that they are a difficult stick, the Interviewer may take the participant to the GCRC for a blood draw, following this procedure:
- Call GCRC at x 46041 to inform them that you will be bringing a participant for a blood draw.
 - Bring blood draw supplies, all blood paperwork, one sheet of barcode labels, HIPAA and consent forms, as well as GCRC admission forms.
 - Once at GCRC make a copy of the HIPAA and consent forms for GCRC and give to one of the nurses on duty.
 - Fill out GCRC admission forms and give to one of the nurses on duty.
 - Have participant fill out the Self-Administered Specimen Checklist.
 - Wait with the participant while their blood is being drawn.
 - Once the blood draw is complete, fill out all blood paperwork.
 - Leave the red and green tubes with the GCRC staff and deliver the purple tube to the basket in room 296 of the Molecular Biology Core laboratory. After 5:00 PM weekdays or on weekends, all tubes will be left with GCRC staff.
6. If an interview is cancelled or no blood specimen obtained, Interviewer will notify both Shen and Rui at x85483, as well as the GCRC at x46041, not to expect a blood specimen. At this time the Interviewer should follow the procedure for the collection of a Saliva Sample (see DNA Collection Section).

10/14/04

Reference: Blood Draw

BLOOD DRAW PROCEDURES

The blood draw should take place in a location which is well-lit and has no carpet. If carpeted, protect the floor with a Chuks. The participant should be comfortable and should be in a place where she will not be injured if she faints, e.g., the couch or chair.

Next, prepare your work area. Carefully drape the area you will be working in because any spills outside the draped area must be cleaned with an antibacterial wipe. Place only the supplies you need for the draw for this subject on the covering. This would include the tourniquet, needles, tubes, alcohol wipes, gauze strips, and band-aids. Keep the Blood Specimen Data Sheet and a pen on the table and complete each section as you proceed.

A. Follow the steps outlined below to **prepare the puncture site**:

- Wash your hands thoroughly with soap and water or use handiwipes, if necessary. Dispose of towels or wipes in a waste biohazard bag.
- Put on gloves.
- Ask which arm the participant prefers to be used for the blood draw.
- Instruct the subject to extend her arm palm up and straight at the elbow so that the veins are accessible and you are able to work in a comfortable position. Be sure that the arm is in a downward position to prevent backflow.
- Inspect the arm you plan to use. The veins of choice are located in the antecubital area. It is preferred that you do not draw blood from the back of the hand.
 - Do not draw blood from an arm which has a rash, open sores, is swollen, or has evidence of a recent blood draw or hematoma.
- Apply the tourniquet about 3-4 inches above the elbow.
- Select a vein which is palpable and well-fixed. Palpate even when the vein can be seen. Avoid veins which feel hard or show signs of scarring.
- If the veins do not distend quickly,
 - Ask the subject to open and close her hand several times;
 - Massage the arm from the wrist up to the elbow;
 - Apply a warm compress for about 10 minutes;
 - Tap the area two or three times; and

- Examine the other arm. Sometimes veins in one arm are larger than in the other.
- If the tourniquet has been applied for more than one minutes while the vein is selected, release it for at least five minutes before re-applying.
- Cleanse the puncture site with an alcohol wipe, working in a circular motion out from the puncture site.
- Dry the area using a sterile 2 x 2" gauze. The area should be dry.

You will make one attempt at drawing the participant's blood. If you are unsuccessful with one needlestick, ask the subject if you can try again. If you are unsuccessful with two needlesticks, you will stop and clean-up the blood draw materials. You will then document the problem. If the interviewee is a patient at a participating hospital, ask permission to contact her at her next doctor's appointment.

B. You will attempt to **collect three tubes**, one red, purple and green for each participant using the following technique:

- Assemble the butterfly with the vacutainer holder.
- Ask the participant to make a fist.
- Remove the shield from the butterfly needle and approach the vein in the same direction the vein runs, holding the needle with the bevel up and at a 15° angle, about ½" below the proposed point of entry to the vein.
- Pinching the butterfly "wings" together, push the needle firmly into the skin and then into the vein. When you are firmly in the vein, blood will appear in the tubing of the butterfly.
- Quickly push the red test tube onto the butterfly needle in the holder puncturing the stopper of the tube. The tube must be punctured in the center of the stopper.

If no blood appears in the tubing, attempt to re-position the needle. If blood does not appear, release the tourniquet and remove the needle, placing a sterile gauze pad over the puncture site.

Ask the participant if you may attempt a second draw. If she agrees, make a second attempt on the other arm with a sterile collection set and new test tubes. Two attempts are allowed, only after verbal consent by the participant.

- Hold the tube with the stopper in an upright position so that the contents of the tube do not touch the stopper.
 - When the first tube is full, remove it from the holder and place succeeding purple and green tubes in holder.
 - If tubes are slow in filling, re-apply the tourniquet and ask the participant to open and close her hand slowly. Release the tourniquet when blood flow has been established.
 - If at any time during the blood draw procedure a hematoma appears, terminate the blood draw.
 - **Remove the tourniquet when the third tube is partially full.** The participant should open her fist.
 - Immediately invert the tubes to ensure proper mixing of blood and anticoagulant. Note: the ratio of blood to anticoagulant in these tubes has been determined for maximum test sensitivity so be sure to fill the tube as completely as possible.
 - If the subject shows any adverse affects or states she does not feel well, terminate the blood draw and follow emergency procedures as necessary.
- C. The following procedures will be followed in **concluding the blood draw**.
- When the last tube is filled and gently inverted, quickly withdraw the needle holding a gauze pad over the puncture site and applying slight pressure only when the needle is withdrawn.
 - Ask the participant to hold the gauze pad with moderate pressure and raise the arm straight up in the air for 2 minutes. Do not flex the arm. If the participant is using a blood thinning medication other than aspirin, have her apply pressure to the area for a few extra minutes.
 - IMMEDIATELY, disconnect the butterfly assembly from the vacutainer holder and discard it in the sharps container. The holder is reusable.
 - If the holder becomes visibly soiled, discard it in the biohazard bag.
 - **Label each tube with an ID label. If the label overlaps itself, be sure that the ID number can easily be read.**
 - Check the puncture site and apply a band-aid over a sterile 2x2" gauze pad when bleeding has stopped.
 - Keep continued pressure on the site for a few more minutes if bleeding continues.
 - Closely monitor the subject for any adverse reactions to the blood draw for ten minutes.

- Discard all used material in the waste biohazard bag.
- Dispose of needles in a sharps container and the gloves, table covering, and handiwipes in the waste biohazard bag.
- Wash your hands with soap and water or an antibacterial handwipe.

NOTE: If blood has spilled on an area outside of the table covering, the area must be washed with an antiseptic wipe. The towels must be disposed of in the waste biohazard bag.

10/14/04
Reference: Blood Draw

UNUSUAL OCCURRENCES

When a problem occurs during the venipuncture, it is important to document this in the comment section of the Blood Specimen Data Form. For example:

- Unsuccessful draw: reasons, how many attempt, etc.;
- Quantity not sufficient;
- Two sticks required;
- Tourniquet left on too long;
- Hematoma developed;
- Subject became ill or fainted;
- Subject requested blood draw be stopped;
- Sample hemolyzed, lipemic, icteric, or clotted;
- Vial cracked;
- Sample leaked; and
- Problems transporting blood to laboratories.

Specimen Storage

There may be times when you are unable to deliver the blood specimens to the GCRC on the day they are collected. In those instances, you will need to store the blood until the next day. Blood specimens are to be stored in a specimen biohazard bag and refrigerated.

Venipuncture Complications

Hematomas

Hematomas are the most common complication of venipuncture. They are masses produced by coagulation of extravasated blood in a tissue or cavity. They may result from through-and-through puncture to the vein or from incomplete insertion of the needle into the lumen of the vein, allowing the blood to leak into the tissue by way of the bevel of the needle. In the latter case, correction may be made by advancing the needle into the vein. At first sign of uncontrollable bleeding, the tourniquet should be released and the needle withdrawn. Mild pressure to the puncture site should be applied immediately. Hematomas also result from the application of the tourniquet after an unsuccessful attempt has been made to draw blood.

Hematomas most frequently result from insufficient time spent in applying the pressure, from failure to apply pressure, and from the bad habit of flexing the arm to stop bleeding. Once the venipuncture is complete, the subject should be instructed to apply mild pressure to the puncture site and raise her arm straight in the air for about two minutes. Constant pressure should always be maintained until the bleeding stops. Pressure should be applied with dry, sterile gauze; a wet sponge encourages bleeding. Band-aids do not take the place of pressure and, if used, are not to be applied until after the bleeding stops.

Arms covered with ecchymoses (escape of blood into the tissues, producing a large and blotchy area of superficial discoloration; bruises) demonstrate poor technique or a haphazard manner. Proper techniques must be employed at all times to prevent unnecessary hematomas.

Syncope (Fainting)

Syncope, or fainting, is a sudden loss of strength or temporary loss of consciousness and is caused by decreased blood flow to the brain. To prevent injury of any subject who might faint, always perform the venipuncture when the subject is in a seated, relaxed position with feet flat on the ground. Warning signs include: the subject may become pale and begins to perspire heavily; the subject may feel dizzy and hot, and may begin to pant (hyperventilate); and/or the subject may feel nauseated.

When the subject has any of the above signs, terminate the venipuncture. Instruct the subject not to watch the procedure. Have the seated subject put her head down between her knees, and carefully prevent her from falling. Have her take slow, deep breaths. Keep talking to the subject in a calm, reassuring manner. Call for a family member or co-worker, if available.

If the subject faints, gently ease the subject to a lying position and elevate her feet. Check radial pulse. After the subject regains consciousness, give her fluids, i.e., water. Stay with the subject until you are assured that she has recovered.

Continued Bleeding

Some subjects are receiving certain drug therapies or have bleeding disorders that may cause them to continue to bleed after the venipuncture. To prevent bleeding, it may be necessary to apply pressure to the puncture site for an extended period of time. If the subject continues to bleed after ten minutes, call her physician for appropriate care.

Thrombosis

Thrombosis is the formation of blood clots (thrombi) inside a blood vessel or inside the chambers of the heart. They can occur as a result of venipuncture when the endothelial lining of the vein is injured. A thrombosed vein should not be used for venipuncture. A thrombosed vein can be detected by palpation prior to the venipuncture. The vein with a thrombosis lacks resilience, feels hard and cord-like, and rolls easily. Remember only the veins in the arms will be used for the venipuncture procedure. Veins in the lower extremities may have poor circulation, which leads to the formation of thrombi.

To prevent thrombosis, subsequent venipunctures should be performed at sites proximal to previous puncture sites.

Sclerosis

Sclerosis is an indication of hardening of blood vessels. It can occur as a result of inflammation, excessive venipuncture, or poor technique. A vein that feels hard when palpated should not be used for venipuncture. Prevention of sclerosis can be accomplished by the skillful performance of venipuncture technique.

Embolus

An embolism is transfer of a mass, blood clot or object within the vascular system, from its point of origin or entrance to a distant site, causing an obstruction of blood flow. The embolus is most often a blood clot, but it may be a fat globule, an air bubble, a piece of tissue, or a clump of bacteria. Embolisms are usually fatal, and can be prevented by performing the venipuncture procedure using skillful technique.

Medical Emergencies Overview

The blood specimen collection component is designed to be safe for all eligible subjects. However, it is possible that an incident or medical emergency may occur when you are conducting a blood draw.

All life-threatening emergencies that may occur during a home visit, such as acute myocardial infarction, should be referred for immediate evaluation at an acute care facility, with emergency measures taken, as needed, prior to departure. Minor emergencies, such as hypotension or fainting, should receive treatment and then the subject should be assisted to contact their physician to determine if further evaluation is needed. Although, most emergencies are of a less severe nature, you should be prepared for both types.

When a serious or life-threatening event occurs during a home visit, your primary goal is to stabilize the subject and assist her to the nearest medical facility. If possible, contact the subject's physician and/or the next-of-kin. If the situation is urgent, 911 should be called and the subject transported to an emergency room. When in doubt, call 911 and report the incident; the emergency personnel will determine whether transport is necessary. As soon as possible, notify Lina Jandorf or Rose Bialecki.

In the event of a medical emergency in which the subject remains conscious, you must obtain the consent of the subject to contact emergency medical services. If the subject refuses to consent, the subject or the subject's guardian must be asked to sign a release form which states that the subject does not wish to contact an emergency medical service for follow up medical attention against the advice of the MSSM technician. If a family member or a neighbor is present, they should be asked to witness the subject's signature by signing the release form.

For incidents requiring the use of emergency medical services, even if the subject was not transported to an emergency care facility, you should meet with your supervisor to discuss the incident.

10/14/04

Reference: Blood Draw

MSSM BREAST CANCER STUDY

INCIDENT/EMERGENCY REPORT

1. Date of Incident/Emergency: _____ Time of Incident/Emergency: _____ AM/PM		2. ID Number: [][][][][] Subject's Age: [][][]	
3. Subject's Symptoms (Please list.) _____ _____ _____ _____ _____		4. Medical/Emergency Procedures Followed: <div style="text-align: right;"><input type="checkbox"/> N/A</div>	
5. Emergency Equipment Used (Please list.) _____ _____ _____ _____ _____		6. Outcome of Medical Procedures Used: <div style="text-align: right;"><input type="checkbox"/> N/A</div>	
7. Identification of Emergency Services Used: <input type="checkbox"/> N/A A. _____ B. _____ _____ _____ () _____			
8. Identification of Medical Facility to Which Subject Was Taken: <input type="checkbox"/> N/A _____ _____ () _____ <div style="display: flex; justify-content: space-between;"><div>Accompanied Subject to Facility</div><div>Y N</div></div> <div style="display: flex; justify-content: space-between;"><div>Personal Belongings Sent with Subject</div><div>Y N</div></div>			
1. Physician Contacted on: _____ Next-of-Kin Contacted on: _____ Specify Next-of-Kin: _____ Supervisor Contacted on: _____			
Any other comments:		Research Interviewer Signature: _____ Date: _____	

10/14/04

Reference: Blood Draw

To complete the form, you should include the following information:

- Month, day, year and time of the incident or emergency.
- Subject's ID number.
- Subject's age (enter number of months or years).
- Subject's symptoms (list specific symptoms separately like shortness of breath, dizziness, chest pain, etc).
- Medical/emergency procedures followed (briefly describe what was done in the order in which it was done; if not applicable enter "N/A"; vital sign measurements would be recorded here if applicable).
- Emergency equipment (list all equipment's used; if not applicable, enter "N/A.")
- Outcomes (briefly describe outcomes of the incident/emergency by relating them to individual procedures performed; if not applicable, enter "N/A.")
- Identification of emergency services used (list specific name, address and telephone number, including area code, of hospital ambulance service or police, fire, county or local rescue squad used; if not applicable, enter "N/A.")
- Identification of medical facility to which participant was taken; if not applicable, enter "N/A.")
- Phlebotomist accompanied (circle appropriate response for whether you accompanied subject to the medical facility).
- Personal belongings (circle appropriate response for whether personal belongings were sent with the subject).
- Month, day and year you contacted the subject's physician/clinic, if known; if not applicable, enter "N/A").
- Month, day, year you contacted next-of-kin.
- Name of next-of-kin contacted.
- Lina Jandorf or Rose Bialecki contacted.
- Your ID (Initials).
- Comment section should include a summary statement of your impression of what occurred with the subject and any additional information that warrants documentation on the report.

10/14/04

Reference: Blood Draw

PROCEDURE TO FOLLOW IN THE EVENT OF NEEDLESTICK/SHARPS INJURY OR OTHER BLOOD/BODY FLUID EXPOSURE

An exposure is defined as:

- A percutaneous injury (e.g., needlestick, cut with a sharp object, bite);
- Contact of blood or body fluids with mucus membranes;
- Contact of blood or body fluids with skin that is chapped, abraded, or otherwise not intact;
- Contact of blood or body fluids with intact skin when the contact is prolonged and involves an extensive area of skin.

1. **Wash** the exposed area immediately with soap and water. If mucous membranes were exposed, e.g. eye splash, **Flush** with water.
2. Immediately **report** the exposure to:

<u>Beeper</u>	<u>Office</u>	<u>Cell</u>
Lina Jandorf:	917-424-0702	212 659-5506 917-650-3751
<u>or</u> Rose Bialecki		212 659-5473 917-607-3195
3. **During regular business hours**, Lina or Rose contacts the **Needlestick Coordinator**, Beeper 4118; from outside MSMC: 212-241-5581 and asks for beeper 4118. Needlestick Coordinator will complete **Risk Assessment Checklist** and review **consent for HIV testing** with participant over the phone.
4. **If not regular business hours**, Lina or Rose contacts the Page Operator at 212-241-6500 to beep the **Nursing Administrator on call for the Dept. of Medicine**. Either she or they complete the **Risk Assessment Checklist** and review **consent for HIV testing** with participant over the phone; also **obtain control participant's physician's name and phone number**.
5. Needlestick Coordinator, Lina or Rose will **notify the lab** to expect the blood sample at the following 659 extensions: 8168;8161;8162 or 8145. Obtain name of contact person.
6. Employee **obtains signature for Informed Consent** for HIV testing and offers copy to participant.
7. Employee draws a blood sample using the **red top test tube** and writes participant's name, DOB and sex on blank specimen label. Blood will be tested for Hepatitis and, if consent obtained, HIV status.
8. Employee reports **within one hour** to Employee Health Service (19 E.101St.) with red top tube or the **nearest Emergency Room**. **Do not leave red tube in ER**. If not during regular business hours, employee will take red top tube to lab on the 8th floor of the East Building, L8-72.
9. Supervisor will complete **Blood/Body Fluid Worksheet** (fax sheet). If not regular business hours, Supervisor will also complete 2 green **Microbiology Lab Virology/ Serology requisition forms** and bring to lab in East Building, L8-72. If during regular hours, Needlestick Coordinator will complete forms. Blue copy of forms will be kept on file.

10/14/04

Reference: Blood Draw

BLOOD PAPERWORK

The following paperwork may be needed for obtaining a blood sample.

The **Specimen Collection Record** and the **GCRC Physician Order Sheet** are filled out for **every** blood sample collected, regardless of the phlebotomist—Interviewer, Participant's Doctor, GCRC staff, etc.

***Specimen Collection Record**

- Top portion should be completed at the time of the blood draw
- One copy (duplicate form) goes with the red and green tubes
- One copy goes with the purple tube
- Note the date and time of GCRC arrival as well

***GCRC Physician Order Sheet**

- Complete upon arrival at GCRC
- Goes in the Biohazard bag with the red and green tubes

Instructions to Participants and Physicians - Given to participants who take a blood kit to their doctor.

The following are used when GCRC staff draw the blood for the Interviewer:

GCRC Request for Admission

- For GCRC blood draws only
- Fill out demographic information as best you can
- Give to GCRC staff

Mount Sinai Hospital Order Sheet

- For GCRC blood draws only
- Make sure you use a copy with a signature
- Write the date of the blood draw next to the signature
- Give to GCRC staff

***Denotes paperwork mandatory for EVERY blood sample collected.**

10/14/2004

Reference: Blood Draw

SPECIMEN COLLECTION RECORD

GCO # 00-730 CA, DHRCC

PATIENT ID# _____
(Bar Code Sticker)



DATE COLLECTED: _____ TIME COLLECTED: _____

INTERVIEWER/PHLEBOTOMIST: _____

NUMBER OF TUBES DRAWN:

RED TOP TUBE (10ML) _____
GREEN TOP TUBE (10ML) _____
PURPLE TOP TUBE (4ML) _____

DATE AND TIME GCRC ARRIVAL: _____

DATE AND TIME GCRC PROCESSED: _____

TECHNICIAN: _____

NUMBER OF NUNC VIALS FILLED



SERUM (5ML) _____ PLASMA (5ML) _____ RED BLOOD CELLS (5ML) _____

CLOTS (2ML) _____ BUFFY COAT (2ML) _____

TIME PLACED IN REFRIGERATOR: _____

PICKED UP BY WHOM: _____

DATE/TIME PICKED UP BY DHRCC LAB: _____

Department Name: Ruttenberg Cancer Center
East Building Room: 16-52; Box 1130
Phone Number: 212-659-5406
Senaka Peter: Project Coordinator

DMSSCR (4/03)

10/14/2004

Reference: Blood Draw

Original Top – GCRC Core Laboratory - Room 256
Yellow Copy – GCRC

GCRC Physician Order Sheet

GCO Protocol #00-730 CA, DHRCC

Behavior, estrogen metabolism, and breast cancer risk: a molecular epidemiologic study

PI: Dr. Christine B. Ambrosone, DHRCC

Co-Investigator: Dr. Julie Britton, Community Medicine

Co-Investigator: Dr. Mary Wolff, Community Medicine

Co-Investigator: Dr. Margaret McGovern, (Ordering Physician), Human Genetics

Project Director: Senaka Peter, MPH

Subject ID# _____

Date of Specimen Procurement: _____ Time of Specimen Arrival: _____ AM PM

Receipt of **1-10mL green top tube** and **1-10mL red top tube**, labeled with ID numbers; additional labels are provided to be placed on all Nunc vials specimens are transferred to. **PLEASE NOTE: after 5PM on weekdays and on weekends**, additional receipt of **1-4mL purple top tube** to be refrigerated and held for pickup with Nunc vials.

There should be a *30 minute* gap between blood draw and centrifugation to allow for clot to form.

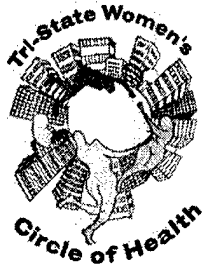
1. Centrifuge all tubes for 20 minutes at 1000g at room temperature.
2. Label all Nunc Vials that specimens will be transferred to with the ID labels provided.
3. From the 10mL **RED TOP** tube:
 - a. Aliquot **serum** into two 5mL labeled Nunc Vials.
 - b. Remove **clot** (cells) and transfer to labeled 2mL Nunc Vial.
4. From the 1-10mL **GREEN TOP** tubes:
 - a. After the spin is complete, 3 layers should be visible. The first layer is the plasma (pale yellow color). Pipette **plasma** and transfer to two 5mL labeled Nunc Vial.
 - b. The middle layer is the **buffy coat** (thin white layer). Carefully collect the buffy coat and transfer into one 2mL labeled Nunc Vial. It is okay to collect the top layer of RBCs in order to ensure all buffy coat is collected.
 - c. The bottom layer is the **red blood cells (RBCs)**. Pipette RBCs and transfer to one 5mL labeled Nunc Vial.
5. Remember to write on all labels the type of specimen that is inside the vial and from which tube it came (*For example*, Serum RTT, Buffy Coat GTT).
6. Place all labeled vials in refrigerator marked for DHRCC breast cancer study.
7. Complete specimen processing form.

PI Signature: _____



10/14/2004

Reference: Blood Draw



Tri-State Women's Circle of Health Breast Cancer Research Project

Instructions to Participants and Physicians

Your patient is taking part in the Tri State Women's Circle of Health Breast Cancer Research being conducted throughout the metropolitan area. She has asked that you, rather than study personnel, draw the blood sample needed for the study. Please follow the steps outlined below which are designed to simplify this process for you and your patient.

- The participant should complete the **Self-administered Specimen Checklist** prior to the blood draw.
- There are three vials in the Styrofoam box, 1 red (10ml), 1 purple (4ml), 1 green (10ml)--all with study ID labels. Please fill all three.
- Please complete the top portion of the **Specimen Collection Record**. Indicate the date and time that the blood was collected as well as who drew the blood.
- Place the vials back in the Styrofoam box and then in the cardboard box. Finally, place the cardboard box in the Diagnostic Specimen Envelope from FedEx, along with all paperwork.
- Complete the sender (From) part of the FedEx USA Airbill. The Sender's FedEx Account Number should already be completed. Mount Sinai School of Medicine, as recipient, will be billed for the shipment.
- Call FedEx at 1-800-463-3339 for same day pick-up of the specimen on **Monday-Thursday**. Specimens cannot be picked up on Fridays.

If it is not convenient to have the Diagnostic Specimen Envelope containing the specimen picked up, it can also be taken to a Federal Express Drop Box on **Monday-Thursday**.

It is important that the blood specimen be mailed the same day it is drawn.

Participant:

On the day of the shipment Please call Senaka Peter at 212 659-5406 or 1-866-223-2219 (toll free) to notify her that a blood specimen has been sent. This will ensure that the specimen will be followed-up on with FedEx should there be a problem.

Thank you for helping with this important research project!

10/14/04

Reference: Blood Draw

ORDER SHEET

PHYSICIAN SERVICE

1. ENTER ALL ORDERS FOR PROCEDURES AND DRUGS FOR THE PATIENT.
2. TO CALL ATTENTION TO THE ORDER, NAME AND DRUGS MUST BE WRITTEN ON "ORDER INDICATOR" SHEET ON FRONT COVER OF ORDER BOOK.
3. URGENT ORDERS MUST BE CALLED TO THE ATTENTION OF THE NURSE IN CHARGE.
4. DOCTOR'S SIGNATURE MUST FOLLOW EACH SET OF ORDERS.
5. TO DISCONTINUE AN ORDER: A COMPLETE NEW ENTRY MUST BE MADE. MEDICATIONS NOT PRESCRIBED AS TO A SPECIFIC DURATION WILL BE STOPPED AFTER FOUR (4) DAYS. CONTROLLED DRUGS (E.G. NARCOTICS, BARBITUATES, ETC.) WILL BE AUTOMATICALLY STOPPED AFTER THREE (3) DAYS.

A - ADMINISTERED
T - TRANSFERRED TO CARDEX
R - REQUEST MADE

RECORD ACTION BY ✓ IN FOLLOWING COLUMN

[illegible]



Mount Sinai School of Medicine
General Clinical Research Center

Request for Admission

GCO# 00-0730

PROTOCOL TITLE Behavior, Estrogen Metabolism and Breast Cancer Risk: a Molecular Epidemiologic Study

Name(s) of Investigator(s):	Dept.	Office#	Home#	Beeper#
1. (PI) Christine Ambrosone, Ph.D.	Cancer Center	212-659-5552		
2. Julie Britton, Ph.D.	Cancer Center	212-241-5488		
3. Margaret McGovern, MD, Ph.D.	Human Genetics	212 -249-9234		

Please circle the number before the name of the attending physician

Name of patient (Last, First, M.I.) _____ Sex _____

(circle): M / F

Birth Date: _____ Birthplace: _____ Marital Status: _____ Religion: _____

Ethnicity (circle): Black Hispanic White Asian/Pacific Islander Native American Other/Unknown

Patient's Street Address: _____

_____ Tel. #: _____

Next of Kin: (name) _____ Relationship: _____

Address: _____ Tel. #: _____

In Case of Emergency Contact: _____ Relationship: _____

Address: _____ Tel. #: _____

Date of Admission: ____ / ____ / Estimated Length of Stay: _____ Days, or 2 _____ Hours

Admission Type (circle): Inpatient/Scatter-Bed/Off-Site/Outpatient Time of Admission: _____ am _____ pm

Prior Registration at Mount Sinai? (Circle): No / Yes, Unit # _____

Admitting Diagnosis: _____

Justification For Admission Under This Study: _____

Activity Level (3):

p Normal ambulatory assistance p Ambulates with assistance p Assistance transferring bed to chair p complete assistance

Dietary (3): p Regular Diet p mg Sodium Diet _____ p Diabetic, (Calories _____) p Kosher

p Low Cholesterol p Low MAO Diet p 1,000 Cal. p OtherN/A _____

I have determined that this patient/subject is a suitable candidate for this research protocol. I estimate the proportion of the admission that will be:

(a) Research 100 % (b) routine care _____ %

Signature of Investigator

Date

The final determination for evaluating what fraction of the admission was for research or routine patient care is made by the Program Direction Staff at the time of discharge.

Request Approved, GCRC

Date

10/14/04

Reference: Blood Draw

VII.
DNA COLLECTION

Procedure

Materials

10/14/04

DNA Collection Procedure

In the event a participant does not agree to provide a blood sample, or if **less than 2** vials of blood can be successfully obtained, a DNA collection procedure will be undertaken, with the consent of the participant. The purpose of this simple procedure is to collect some loose cells from the mouth of the participant.

If blood cannot be obtained from either a Case or Control, they will be asked if they would be willing to have their physician draw the blood during a routine visit. (See procedures for Physician Blood Draw in previous section.) Whether or not they agree to have their physician obtain a blood sample, DNA should be taken as a precaution.

Preferably, the participant will not have had anything to eat or drink other than water an hour before the following procedure.

1. 10 ml. of Scope will be pre-measured into a specimen jar. Instruct the participant to pour the mouthwash from the jar into her mouth, **without swallowing**.
2. Tell her to swish (gargle) the mouthwash around in her mouth vigorously for 60 seconds. **Watch the clock while she does this.** It is important that you do not shorten the time, but there is no harm in doing it for longer than 60 seconds.
3. Have the participant spit the mouthwash back into the jar. Replace the cover on the jar and screw it on **tightly**.
4. Write the date the saliva sample was taken on the label affixed to the specimen cup.
5. Place the container with the sample into the plastic bag. **Push the air out of the bag before sealing it.**
6. Specimen will be delivered to Room 296, 1184 Fifth Ave., and left in the basket between 9:00am and 5:00pm. After 5:00pm and on weekends, specimen will be delivered to the -20 freezer next to the carbon dioxide tanks in L 16-07, East Building, and placed in the door of the freezer. Delivery will be noted in the Specimen Logbook and Shen and Rui, x85483, informed via voicemail of the specimen collection.

DNA COLLECTION MATERIALS

- Peppermint Scope mouth wash
- A specimen jar with 10 ml. of Scope pre-measured into the jar.
- A plastic biohazard specimen bag
- Freezer-resistant label with ID and date of collection printed on it

10/14/04
Reference:DNA

VIII.

Personnel Resources

Buddy System

Staff Listing

10/14/04

BUDDY SYSTEM

The “buddy system” was developed to enhance communication between interviewers and recruiters throughout the recruitment phase. Therefore, each interviewer is matched to a recruiter. If recruitment packets are mailed to recruiters, interviewers will contact recruiters to inform the recruiters of how many potential subjects they are mailing to the recruiter as well as how many are **priority**.

Neon labels will be attached to those cases which must be contacted immediately (within 48 hrs). If a recruiter cannot reach a priority case within this amount of time, they need to contact their interviewer buddy, to let them know. This way, the interviewer can assist the recruiter. It is imperative that we do not lose any potential subjects, due to the late diagnosis date.

Whether or not there are new subjects packets to send, interviewers will contact their recruiter buddies once per week, to see how they are, to ask about recruitment progress, and to see if they have any questions or problems.

Recruiters have **14 days** from the “mail date” to contact their potential subjects. After 14 days, recruiters should return the information in the postage paid envelope

10/14/04
Reference:Personnel Resources

RECRUITER/INTERVIEWER BUDDIES

Interviewer: Rose Bialecki	Sherly Jacob	Melissa Solis	Nadine Robinson
Active Recruiters:			
Iris Mendez (718) 798-5345 (917) 447-3976 (cell)	Carol Copeland (212) 864-0867(H) (212) 234-1447	Alice Jaworsky (718) 721-1355	
	Pat Drew (212) 410-1309	Cathy Williams (718) 981-1673 (H) (347) 728-8289 (cell) (718) 981-8680 (W)	
	Glorie Browne (212) 368-3868 (917) 913-0120(cell)		
Inactive Recruiters:			
Marcia Butler (718) 937-4220	Beverly Coll (717) 484-4263 (H) (718) 812-1020 (cell)	Eileen Abiola (718) 816-1655	
Valerie Ingoglia (718) 728-1867	Lucille Hartmann (718) 626-0831	Medina Byars (718) 430-4167/9(W) (718) 542-0288 (H)	

10/14/04

Reference: Personnel Resources

STAFF LISTING

	<u>Office Number</u>	<u>Mobile Phone</u>	<u>Beeper</u>
Lina Jandorf, M.A., Principal Investigator, Core A	(212) 659-5506	(917) 650-3751	(917) 424-0702
Christine Ambrosone, Ph.D., Principal Investigator, Project 1	866-223-2219		
Heiddis Valdimarsdottir, Ph.D., Principal Investigator, Project 2	(212) 659-5559		
Dana Bovbjerg, Ph.D., Principal Investigator, Project 3	(212) 659-5562		
Julie Britton, Ph.D. Co-Investigator, Project 1	(212) 241-5488		
Senaka Peter, M.P.H., Project Coordinator	(212) 659-5406		
Rose Bialecki, B.A., Field Work Supervisor	(212) 659-5473	(917) 607-3195	
Sherly Jacob, B.A., B.S., Research Interviewer	(212) 659-5405	(917) 650-4835	
Melissa Solis, B.A., Research Interviewer	(212) 659-5540	(917) 519-8031	
Nadine Robinson, M.P.H., Research Interviewer	(212) 659-5513	(917) 519-9425	

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Reference: Personnel Resources

IX.
INTERVIEWER CHECKLISTS

Checklist

Post-Interview Checklist

INTERVIEW CHECKLIST

PRE-INTERVIEW

- ☐ Call participants prior to interview to confirm
- ☐ Maintain interview schedule in database daily.
- ☐ Mail directions, if needed
- ☐ E-mail changes in weekly schedule to: L. Jandorf, R. Bialecki and Shen and Rui
- ☐ Reserve interview room
- ☐ Charge Phone and Check Battery
- ☐ Call office upon arrival if location off-site
- ☐ If interview cancelled: Notify GCRC Nurse Practitioner at X46041; Shen and Rui, x85483; and delete room reservation on KP Calendar. If interview at another hospital site, notify appropriate personnel.

BAGCHECK

- ☐ ID badge
- ☐ Phone
- ☐ Business Cards
- ☐ Interviewer Organizer
- ☐ Interviewer Folio
- ☐ Metrocard
- ☐ Street Map
- ☐ Directions to Interview Location
- ☐ Laminated Primary & Secondary Contact Information
- ☐ Gift certificate
- ☐ Brochures, including Projects 2, 3
- ☐ Participant ID labels (2 sheets/interviewee)
- ☐ Pencils
- ☐ Pens
- ☐ Rubber Bands
- ☐ Pack of "flags"
- ☐ Small note pad
- ☐ Federal Express envelopes
- ☐ Anthropometry Measurement Tools:
 - ☐ Anthropometry Training Manual
 - ☐ Mastik tape
 - ☐ Gulick II Tape Measure
 - ☐ Triangle
 - ☐ Tanita Scale
 - ☐ Extension cord
- ☐ Blood draw items:
 - ☐ Tourniquet
 - ☐ Chuks pads
 - ☐ Test Tubes (1 red, 1 purple, 1 green); take extras

- ☐ Vacutainer Holder
- ☐ Alcohol pads
- ☐ Gauze
- ☐ Band-aids
- ☐ Butterflies
- ☐ Gloves
- ☐ Sharps container
- ☐ Biohazard Disposal trash bags
- ☐ Non-biohazard trash bags
- ☐ Styrofoam Transport Box
- ☐ Paper Towels
- ☐ Antibacterial Wipes
- ☐ DNA items:
 - ☐ Specimen jar with 10ml. Peppermint Scope
 - ☐ Biohazard Bag
- ☐ Forms
 - ☐ Project 1 Consent; Project 2 Telephone Consent
 - ☐ Interview Questionnaire; include extra Physical Activity Sheets
 - ☐ List of Activity Codes
 - ☐ Show Cards
 - ☐ Food Frequency Questionnaire
 - ☐ Early Life Experiences
 - ☐ Behavior Change
 - ☐ IES
 - ☐ How I Feel Scale
 - ☐ Specimen Collection Checklist
 - ☐ Specimen Collection Record
 - ☐ Projects 2 and 3 Materials
 - ☐ GCRC Admission Form
 - ☐ GCRC Orders Form
 - ☐ Envelopes, stamped/addressed to MSSM for self-report scales
 - ☐ Incident Report Form
 - ☐ HIV Test Consent
 - ☐ Mental Health Inventory Summary Sheet

POST-INTERVIEW

- ☐ Notify office of departure (if offsite)
- ☐ Bring blood specimen to GCRC and Lab Rm. 296 and DNA to Lab Rm. 296 or East Building, Rm.16-07
- ☐ Record specimen transport and delivery time/date in GCRC Logbook;
- ☐ Review questionnaires for completion and accuracy
- ☐ Enter Post-Interview Checklist into database
- ☐ Complete Mental Health Inventory Summary Sheet; distribute and enter in database.
- ☐ Distribute consent form and questionnaires to Senaka Peter, including those of Partial Interviews.
- ☐ Re-stock carry-all and/or interview room

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Reference: Interviewer Checklists

POST-INTERVIEW CHECKLIST

Interviewer ID: _____ **Date:** _____
Participant's ID: _____ **Date Interview Completed** _____

DOB: _____ Age: _____ Case/Control Race: _____
Referring Hospital: _____

Location of Interview:

MSMC Department: GCRC _____
1176 _____
East Bldg. _____
Other _____

Hospital: St. Luke's _____
Kings County _____
Queens-Mt. Sinai _____
Einstein/Monte/Jacobi _____
New York Hospital Queens _____
Beth Israel _____

Participant's Home: Other:

Interview Sections:

- 1 - Complete
2 - Partial
3 - None
4 - Missing

- ☐ **Consent Form and Contact Sheet**
- ☐ **Main Questionnaire**
- ☐ **FFQ**
- ☐ **Behavior Change**
- ☐ **Early Life Experiences**
- ☐ **IES**
- ☐ **How I Feel Scale**
- ☐ **Blood Draw**
- ☐ **DNA**
- ☐ **Anthropometry Measurements**
- ☐ **Incident Report on File**

Date Submitted: TO
 _____ SP
 _____ SP
 _____ SP
 _____ SP
 _____ SP
 _____ SP
 _____ SP
 _____ SP
 _____ **GCRC; Rm. 296**
 _____ **15-76, East Bldg.**
 _____ SP
 _____ LJ

Interview Status:

- 1 _____ Completed
2 _____ Partial, Pending Completion
3 _____ Partial, Final

Eligible	Material Given	Signed Consent
----------	----------------	----------------

Project 2

Project 3

Gift Card Serial Number 1:	Metrocard: Yes No
-----------------------------------	-------------------------------

Gift Card Serial Number 2: _____

Date Thank You Mailed: _____ **Contact Future Studies: Yes** _____ **No** _____

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Reference: Interviewer Checklists

X.

Hospital Information

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XI.

Project 2

XII.

Project 3

XIII.

Addendum

Consent Forms

Questionnaires

Specimen Checklist

Show Cards

Field Materials

Primary/Secondary Contact Information

Question by Question Specifications

Needlestick Paperwork

Anthropometry Training Manual

Physical Activity Codes



Breast Study

Recruiter Training Manual

10/14/04

Recruiter Training Program

Agenda

5:30-5:45	Introductions
5:45-6:00	Volunteer Office
6:00-6:15	Overview of Project
6:15-6:30	Interviewers' Role <ul style="list-style-type: none">- Buddy System
6:30-7:00	Recruiters' Role <ul style="list-style-type: none">- Confidentiality- Contact List- Paper Trail- Resource Guide
7:00-7:30	Role Playing

Thank you for your willingness to participate and help us with our study!

II.

Why This Study?

Program Description

10/14/04

Reference: Study Description/Goals

DESCRIPTION OF BREAST CANCER STUDY

More and more women are being diagnosed with breast cancer. One out of every eight women will develop breast cancer in her lifetime. African-American women often develop breast cancer at an early age (before age 50) and sometimes the disease is more serious than in Caucasian women. For Hispanic women, breast cancer is the most commonly diagnosed cancer. This research project is to help us understand the causes of breast cancer. What people eat and drink and other lifestyle habits could affect their health. But not everyone with similar habits will get sick. This may be because of differences in how their bodies respond to things that they eat, drink, and smoke; and medications they take. In these studies, we will ask the same questions of women with breast cancer ("Cases") and women without cancer ("Controls"), who are the same age and live in the same area. They will be asked questions about eating, drinking, exercise and smoking habits, their medical and family histories, and other behaviors which may protect against or otherwise affect disease. Measurements will be taken, including height and weight. Comparisons between women with breast cancer and those without cancer will then be undertaken to determine differences.

Blood will also be drawn, (about 2 tablespoons). This blood will be processed to measure differences in how the body deals with things we eat, drink and smoke. Just like the answers to the questions, ways in which people break things down will also be compared between women with breast cancer and those without. From this study we hope that we will be able to see what some of the causes of breast cancer might be.

10/14/04

Reference: Study Description/Goals

Tri-State Women's Circle of Health

BREAST CANCER STUDY

GOALS

To find out more about

1. Why some women get cancer and others do not
2. Why some women have cancers that make them die sooner than other women
3. Why some women get the disease at young ages (less than age 50)
4. What things in the environment, in our diets, and in our genes affect these outcomes
5. Effective ways to encourage women to participate in the study

10/14/04

Reference: Study Description/Goals

ABOUT THE STUDIES

“Core A” is the name of the Recruiting and Interviewing portion of the three research projects, each of which addresses an important issue in breast cancer research.

Principal Investigator: Lina Jandorf, M.A.

These 4-year studies looking at critical psychological or behavioral issues will improve our understanding of the causes of breast cancer. The studies are:

Project 1: “Behavior, estrogen metabolism, and breast cancer risk: a molecular epidemiologic study.” Principal Investigator: Christine Ambrosone, Ph.D.

This is a study to understand why some women get breast cancer and others do not.

Project 2: “Impact of culturally tailored counseling on psychobehavioral outcomes and BRCA decision making among African-American women with breast cancer.” Principal Investigator: Heiddis Valdimarsdottir, Ph.D.

Women from Project 1 whose family history suggests that their cancer may be inherited will be offered genetic counseling and genetic testing at no cost. Such counseling may reduce distress and increase knowledge about breast cancer, genetic testing, and breast cancer prevention and surveillance options.

Project 3: “Immune surveillance, stress, and inherited susceptibility to breast cancer: a psychobiological analysis of the healthy daughters of breast cancer patients.”

Principal Investigator: Dana Bovbjerg, Ph.D.

The adult daughters of women with breast cancer from Project 1 will be compared with the adult daughters of women without breast cancer to examine the possibility that inherited deficits in the immune system may be related to familial risk among daughters of patients whose cancers are not related to mutations in BRCA1 or BRCA2 genes.

10/14/04

Reference: Study Description/Goals

What Will You Do?

**Barriers to Participation in Research Studies
Benefits to Participation**

**Your Message to Participants:
“DIB”**

Decisions, Involvement, Benefits

Counseling Guidelines

10/14/04

Reference: Role of the Recruiter

BARRIERS TO PARTICIPATION IN STUDIES AND RESEARCH

- Poverty; lack of education
- Time and hassle from patient's perspective
- Negative personal and family attitudes
- Not feeling well, too overwhelmed
- Inadequate evidence of benefits
- Protocol too invasive (e.g. blood draws)
- Too much time required to participate
- Fearful about research, being a "guinea pig"
- Information about the study is too technical and too complex to be easily understood

BENEFITS TO PARTICIPATION IN RESEARCH

- Help ourselves by facilitating breast cancer research
- Help our children/grandchildren
- Knowledge – research is the key to opening doors for more information, particularly for women from minority ethnic groups who have been under-represented in research in the past. For example, African-American women with breast cancer are frequently diagnosed at a younger age, with more advanced, aggressive tumors. There are many possible reasons for this but only research will help give us the answers why and allow us to begin to identify means of prevention.
- Participating in research is an opportunity to give something back to others, in particular, other women.

10/14/04

Reference: Role of the Recruiter

YOUR MESSAGE TO PARTICIPANTS AND MATCHED HEALTHY WOMEN

“DIB”

DECISION, INVOLVEMENT, BENEFITS

Decision

When you talk with women, one of the areas you will discuss is why they may choose to participate in the research and what is their decision-making process.

Guidelines:

- Focus on the experience – What will she consider in deciding?
- Share the important fact that influenced you – Who or what things helped you decide that it is important to know WHY women get cancer?
Why YOU or SHE got cancer.
- Share the difficulties and issues. What are the issues that may affect their decision?

Reasons you would want to participate:

1. _____
2. _____
3. _____
4. _____
5. _____
6. _____
7. _____
8. _____
9. _____
10. _____

Other reasons given during discussion:

Involvement

It is important for you to share with patients and controls what is **involved** in the study experience – the issues which affect her decision to participate in a study.

Guidelines:

- Give the patient a “picture” of the experience – don’t frighten them, but let them know the kinds of things involved in the study experience.
- Help them feel informed about what to expect

List some of the things that are involved in the research process:

Benefits

Be sure to tell the patients all of the good things about the research, and what you perceive to be benefits of participating in a study like this.

Guidelines:

Mention two or three of the most important things – what do you consider to be the top three benefits?

List the benefits of participating in this study:

1.

2.

3.

4.

5.

10/14/04

Reference: Role of the Recruiter

Recruiting for Studies

How to Give Advice and be Listened to: Counseling Guidelines

As a breast cancer survivor, you may know a lot about your cancer experience and treatment, but recruiting other patients and women to participate in research about the cause of cancer may require new skills for you. You may get into discussions with women that require some counseling skills. Here are a few tips on how to counsel effectively. Some of these suggestions you may already know. Others may be new to you.

Counseling/Recruiting Guidelines

- Be supportive and non-judgmental-nothing she says is bad or stupid.
- Ask open-ended questions that can't be answered with yes or no. Questions that begin with why, what, or how for example, will give fuller answers.
- Make sure the questions you ask are ones you can and would answer yourself. Don't ask questions that are too technical or too personal.
- If there is a disagreement, don't defend or argue. Ask more questions to broaden the perspectives. For example, *why do you think that...? Are you worried/afraid that...?*
- Because you are a survivor, she might want you to tell her what to do. It is not your role and you will not be trained to counsel regarding treatment or how to cope.
- Reflect back to her what she has said, especially if you are unsure about what she means or if she seems unsure of herself. For example, *So you feel/think that....*

10/14/04

Reference: Role of the Recruiter

Recruiter Role

How to Give Information and be Listened to: Research Study Discussion

The guidelines on the previous page help create a sense of trust and a positive tone in a discussion session. It is also important to direct the discussion in such a way that you know what kind of information is needed. Here are some guidelines for directing your discussion:

- Find out what concerns she already has
- Find out what she knows about research or epidemiological studies. Does she worry about being a “guinea pig”? Does she think it is risky? What does she know about others’ experience?
- Find out how she feels about participating in research in general. Does she have any fears about the blood drawing or contamination of her blood?
- Use the DIB guidelines – Decision, Involvement, and Benefits
- Encourage her to think about the issues and talk with you and the study staff about them.
- Leave her with information and a phone number to call. Tell her you’ll check back with her in a week or so (if appropriate) and encourage her to call Rose Bialecki about questions: (212) 659-5473.

Talk about the different kinds of questions suggested here. A good recruiting session will:

- get the facts
- discuss feelings and give emotional support
- give facts/informational assistance
- help solve problems
- guide a decision

Recruiting Techniques Exercise

Working in groups of two or three, fill in the spaces provided with one or two additional questions that will help you reach the counseling goal listed to the left.

<u>Goal</u>	<u>Questions or Statement</u>
1. Get the facts	<p>What do you understand about this study?</p> <p>_____</p> <p>_____</p> <p>_____</p> <p>_____</p>
2. Discuss feeling and give emotional support	<p>How do you feel about participation in this kind of research?</p> <p>_____</p> <p>_____</p> <p>_____</p> <p>_____</p>
3. Give facts/informational assistance	<p>I am a survivor. We are all interested in knowing more about what causes cancer. This study can help us understand why some of us have cancer and other women don't.</p> <p>_____</p> <p>_____</p> <p>_____</p> <p>_____</p>
4. Help solve problems	<p>Do you have enough time to participate?</p> <p>_____</p> <p>_____</p> <p>_____</p> <p>_____</p>
5. Guide a decision	<p>Do you have questions I can answer?</p> <p>_____</p> <p>_____</p> <p>_____</p> <p>_____</p>

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Reference: Role of the Recruiter

IV.

How Will You Do It?

General Telephone Techniques

Contact Issues

Questions/Answers

Sequence of Actions

Tri-State Women's Circle of Health Flow Chart

Contact Sheets

Participant Recruitment Forms (Cases/Controls)

Questionnaire for non-Participants

10/14/04

Reference: Recruiting Tools/Techniques

General Telephone Techniques

Since your first contact with prospective participants will be a brief telephone conversation, it is especially important that you strike the correct tone within the first few minutes. This section contains a discussion of the techniques to use and procedures to follow when making your first contact by telephone.

When you visit people in person, your body language and your appearance help you communicate and maintain cooperation. By your posture, facial expressions, gestures, and other body language you present a non-threatening, neutral, yet supportive impression. Similarly, when interviewing in person, you have the opportunity to observe the woman's facial expressions and body language to see how she is reacting.

When you are contacting people over the telephone, you do not have these advantages. You cannot observe the woman and she knows only your voice. Because of this, you may find telephone work to be more challenging than in-person work.

To be successful during a telephone contact, **you need to develop a professional telephone manner and use your voice effectively.** You want to be confident, enthusiastic, warm, and sincere. You want your voice to sound pleasant, and have variety in both the rate at which you speak and also the inflection of your voice. In this way, you can establish and maintain rapport without being there in person.

Several characteristics make up a professional telephone-interviewing manner. They are:

- **Being "On the Job".** It is important for you to be well prepared before starting the conversation. This includes having a quiet, private place from which to call, as well as the time needed to make the call effective. Setting the stage for your contact with this person so you are calm, organized and unhurried will get you off to the best possible start.
- **Voice Quality.** This is how you sound to a listener. Over the telephone, your voice is all that represents you, the study sponsors, and the study to the woman with whom you're speaking. What will a listener hear? Do you have a voice that is clear, pleasant, and easy to understand? Do you speak at a comfortable pace for a listener? Do you speak in a monotone or do you sound like you are interested in the person? Before you begin your telephone calls, think about the sound of your voice and how you might improve it.
- **Concentration.** You need to listen to and concentrate on what the contact is saying so that you won't lose track of where you are in the interview. It is easy to be distracted by noise and also by thinking about what you need to do next. Try to concentrate on the response and let the questionnaire guide you.
- **Enthusiasm.** If you sound like you are truly interested in the study and in each person, she will sense this. The listener may be more likely to think that it is important that she participate.

- **Neutrality and Tact.** Although you want to sound interested in the person, remain neutral and objective. An overly friendly manner can give the listener the impression that you are trying to sell them something.

When you read an introduction, make sure that you do not insert question marks at the ends of sentences that do not have question marks. Introduce yourself quickly and continue with a description of the study. Do not pause long enough for the contact to start to refuse or ask questions until you have the full introduction.

If a woman begins to digress, be attentive to the individual's needs, but don't be overly empathetic or sympathetic. Get back to the subject matter at hand by showing her that you have heard and understood what she has said, but not by expressing a personal view or attitude.

Do not react negatively or abruptly to the listener's statements. An unpleasant telephone manner may disrupt the climate of the conversation and damage the rapport that has been established. No matter what situation arises the Recruiter must always come across as a responsible person doing her job.

The following points summarize all that has been said. These points should serve as a quick guide to a more effective and professional telephone personality.

- **BE PROFESSIONAL.** Be prepared by focusing on the work at hand, with materials ready, time available and privacy assured.
- **BE EXPRESSIVE.** Speak at a moderate rate and volume, but vary the tone of your voice to add vitality and emphasis to what you say.
- **BE DISTINCT.** Pronounce your words clearly and carefully. Always speak directly into the telephone.
- **BE ALERT.** Be cheerful and wide-awake, and listen. This sets the tone of any conversation and shows you are listening.
- **BE NATURAL.** Use simple language. Avoid slang and technical terms when answering subject questions.
- **BE PLEASANT.** Show that you are interested. However, never get too personal.
- **BE COURTEOUS.** Good telephone habits are good manners.

10/14/04

Reference: Recruiting Tools/Techniques

CONTACT ISSUES

A major concern of this and other important research efforts is achieving high response rates. In general, high response rates suggest that more confidence can be placed in the data results. The issues covered here help track and promote response/cooperation.

Completing the Record of Calls

It is important that you are thorough and precise in recording all attempts to contact the case/control whether or not you are able to reach her. The Breast Study Contact Sheet is the principle form designed to document the results of all contact attempts.

Handling Refusals and Other Nonresponse

Overview

You will find that most individuals are very willing to participate in the study. Some will not refuse outright, but will express hesitancy, reservation, or even some initial hostility. Others will put off scheduling an appointment, or habitually cancel their appointment. Still others may leave their house on the day of the appointment to avoid being interviewed. Some individuals will express interest in the study, but will be unwilling to arrange an appointment because of a specific conflict (e.g., vacation plans).

With experience comes sensitivity to the various ways women say "No" and to the manner and wording they use that provide clues to the firmness of a refusal. The more you are aware of these differences, the better you will be able to deal with resistance. The better you understand how cases/controls view you and the study, the better able you will be to reassure them and respond to their objections. It is often the way you handle questions (either verbalized or implied) that makes the difference between getting cooperation or a refusal. Your job is to "read" (during your initial and follow-up contact) the various types of women selected for the study and decide on an appropriate course of action.

Breast Cancer Patients

We believe that breast cancer cases will be very motivated to participate in the study. Any reluctance by cases to participate may come from the timing of the study – not the study itself. Certainly, this is a difficult time for these women. However, **we believe that several reasons will motivate/promote case participation.** They are:

1. The importance of breast cancer to women across the country;
2. The high incidence of breast cancer among African American and Hispanic women;
3. The fact that "case" physicians have provided consent; and

4. You – experienced breast cancer survivors, trained in telephone recruiting.

On the other hand, we know that some cases will express emotions from surprise to tears to anger about being contacted so quickly after their diagnosis. Some cases may not have shared their condition with their friends or family yet. For others, this diagnosis may be an additional concern added to other problems they face. Furthermore, they may be in the process of selecting the type of cancer treatment they will undergo or actually be in the midst of treatment. Your task is to be aware and sensitive to these issues while still endeavoring to follow the study protocol – to obtain agreement to participate in the study.

Controls

Obtaining participation from individuals who are controls present a unique challenge. Population- based controls have fewer motivations than cases for donating their time for research purposes. Therefore, to obtain cooperation, you should appeal to:

1. Their interest in contribution directly to the general advancement of breast cancer research;
2. The specific goal of understanding the role of selected environmental and biological factors in the development of breast cancer among women.
3. Their altruism; and
4. The fact the most respondents enjoy and value their participation.

Remember that the initial telephone contact with prospective participants is your first opportunity to begin to **establish rapport and secure compliance!**

Averting Refusals

There are a number of key suggestions to help you avoid refusals:

In the participant's eyes, you are the study. If they have good feelings about you, they will participate in the study. Encourage positive feelings as follows:

- Be enthusiastic about the study;
- Make it clear you are committed to the project and that you think it is worthwhile;
- Refer to the sponsorship of the study. Mention the letter;
- Emphasize that you are not selling anything or soliciting for any charity;
- Know the study. If you are confident and knowledgeable, your contact will trust you.

10/14/04

Reference: Recruiting Tools/Techniques

QUESTIONS/ANSWERS

1. I don't have time/interview is too long:

I know that this takes a bit of time but there are still many things that health educators and researchers don't know about women and breast cancer. This information is important in helping us to better address the needs of communities like yours. In order to complete the interview, we can work around your schedule. Your help is so important to us because the information you give us about your lifestyle and family and medical history could help us to reduce the number of people who develop and die from breast cancer.

2. I don't have breast cancer; this doesn't really apply to me:

You do not have to have breast cancer to be eligible to complete this interview. We are asking healthy women to participate so we can understand the differences between women who develop breast cancer and those who do not. Your help is so important to us because the information you give us about your lifestyle and family and medical history could help us to reduce the number of people who develop and die from breast cancer.

3. I had a bad experience with (their doctor or a hospital).

I'm sorry to hear that. Problems in getting health care are some of the most frustrating ones, but we hope to interview people like you who have had bad experiences with these health care centers. We need to know if experiences like that can keep people from getting the care they need, such as cancer tests. Your help is so important to us because the information you give us about your lifestyle and family and medical history could help us to reduce the number of people who develop and die from breast cancer.

4. I don't know how this information is going to be used/don't know who will see my answers:

All the information you give to will be confidential. Your interview answers will not be marked with your name, but with a code number. Any personal information we obtain from you will be separated from your interview answers. Your help is so important to us because the information you give us about your lifestyle and family and medical history could help us to reduce the number of people who develop and die from breast cancer.

5. I'm not interested:

I don't know if you've had any family members or friends who have had breast cancer, but the lifetime risk for women to develop this disease is 1 in 8. So even though you wouldn't benefit yourself from this study, your help is so important to us because the information you give us about your lifestyle and family and medical

history could help us to reduce the number of people who develop and die from breast cancer.

6. I don't feel well enough/don't want to travel to any of the hospitals.

If you are unable to come to the hospital, I can arrange for an interviewer to meet you, either at your doctor's office or even to come to your home.

7. I work Monday-Friday; can you do the interview on a weekend or in the evening?

Absolutely. I can schedule a weekend or evening appointment for you with one of our interviewers.

8. Why do you need to take my blood; what will you do with it?

The purpose of the study is to try to understand why some women get breast cancer and others do not. Not everyone with similar habits or characteristics will get breast cancer. This may be because of individual differences in how our bodies make the substances needed to keep everything working right. Just as people differ from one another in how they look, they also differ in what goes on inside their bodies and in how their bodies respond to things they eat, drink and smoke, as well as medications they take. In this study, we will compare some of these factors between women with breast cancer and women without.

9. I'm receiving chemotherapy right now/just finished treatment; can I still participate?

This is not a treatment study and your involvement will not interfere with any treatment you may be undergoing/have recently completed. The study consists of a one-time interview, at which we would take a small blood sample, as well as body measurements. That's all there is to it.

10. I'm not sure what kind of skin cancer I had.

Basal cell or squamous cell carcinoma rarely metastasize in contrast to melanoma which may result in metastasis.

10/14/04

Reference: Recruiting Tools/Techniques

Sequence of Subject Recruitment

1. Cases are identified by:
 - Physicians or their staff directly
2. Controls are identified by:
 - General public controls are identified by an RDD (random digit dialing) company through phone lists
3. Cases are recruited by Physicians' staff directly after their initial diagnosis. Informed consent may be obtained and blood drawn at that time.
4. Controls are assigned to recruiters. Packets are given to recruiters and include:
 - Contact sheets
 - Scripts for phone call
 - Reimbursement forms
 - Self-addressed stamped priority mail envelopes from MSSM
 - Refuser Questionnaires
5. For controls a letter, brochure and post-card with the recruiter's picture and name will be sent by MSSM staff.
6. Recruiter will contact subjects within 14 days if possible.
 - At any time, recruiter may call MSSM staff for assistance with subject phone numbers that may be incorrect. Interviewer will attempt to find current phone number and advise recruiter.
7. Recruiter notifies interviewer of interview date and location by phone or e-mail and interviewer forwards travel directions to participant.
8. Recruiter returns the completed contact sheet back to MSSM.

10/14/04

Reference: Recruiting Tools/Techniques

TRI-STATE CIRCLE OF HEALTH FLOW CHART

	Subject Identification	Recruitment Letter/Brochure Sent/Given	Recruiter Activities Step 1	Recruiter Activities Step 2	Recruiter Activities Step 3
Hospital cases	MD	given directly by MD, MD staff or on-site interviewer	After eligibility confirmed by Project 1, LJ assigns Recruiter and sends postcard	RB sends contact information to Recruiters who call to arrange interview appointments.	Recruiters notify Interviewer; return Recruitment and Reimbursement Forms to RB
RDD controls	phone list	Mailed by Project 1			

After completion by Recruiter, Recruiter Contact Form distributed to Interviewer by RB for appointment confirmation, lab notification, interview, recruitment for additional studies.

10/14/04
Reference: Recruiting Tools/Techniques

Date assigned _____

Date to notify MSSM staff
& return contact sheet

Date recruiter returned
contact sheet to MSSM

**MSSM BREAST CANCER RESEARCH
CONTROL CONTACT SHEET**

ID NUMBER: _____ REFERENCE DATE _____ AGE: _____

PARTICIPANT'S NAME: _____

PHONE NUMBER: _____ ETHNICITY: _____

PARTICIPANT'S ADDRESS: _____

BEST DAY TO CALL: _____ BEST TIME TO CALL: _____

REFERRED BY: RDD _____ FRIEND _____ HOSPITAL _____ (NAME)

RECRUITER'S NAME: _____

INTERVIEWER'S NAME: _____

SCHEDULED INTERVIEW DAY: _____ DATE: _____ TIME: _____

ATTEMPTS

Date	Time	Comments	Participation		Meeting Place		
			Yes	No	Home	Hospital	Other

Recruiter, please check the following words that apply to the participant you called. Also write down any additional comments that the participant made or your feelings about your conversation.

- | | | |
|--|------------------------------------|--|
| <input type="checkbox"/> Enthusiastic | <input type="checkbox"/> Nervous | <input type="checkbox"/> Not sure if they want to participate |
| <input type="checkbox"/> Excited | <input type="checkbox"/> Hesitant | <input type="checkbox"/> Would like more information about the study |
| <input type="checkbox"/> Willing to help | <input type="checkbox"/> Angry | <input type="checkbox"/> Questions for staff about the study |
| <input type="checkbox"/> Pleasant | <input type="checkbox"/> Depressed | |

Additional Comments: _____

If Answering Machine: "I'm calling regarding a study at Mount Sinai and I will call back (specific time) or you may reach Senaka Peter at Mount Sinai by calling 1-866-223-2219 or 212 659-5406."

10/14/04

Reference: Recruitment Tools/Techniques

ID NUMBER _____

REFERENCE DATE _____

Please attempt to call subjects at least once between 9-11a.m.; 1-5p.m.; and 7-8 p.m. before determining whether you can reach them. Please attempt to contact this subject at least 5 times before _____. (return date)

PARTICIPANT RECRUITMENT FORM
[FORM FOR CONTROLS, WOMEN WITHOUT BREAST CANCER]

Hello, may I speak with _____
(WOMAN'S NAME)

If she is not there "When would be a better time to reach her, or is there a better number? I am trying to follow up on some information sent to her about a study at Mt Sinai School of Medicine."

(ONCE WOMAN IS ON THE PHONE):

Hello, my name is _____. I'm a volunteer involved with outreach for the Mount Sinai School of Medicine. A while back, you received a phone call regarding Dr. Christine Ambrosone's breast cancer research. At that time, you agreed to be called to learn more about an on-going study about breast cancer and that is why I'm calling today. Do you remember receiving information about the study, as well as a postcard from me, in the mail? Do you have five minutes to talk? If you have time now, I would like to tell you more about it.

If no:

ASK FOR A BETTER TIME TO CALL BACK. TIME: _____ Day of the Week: _____

If yes:

Before we go on, it is important that you know we are only looking for women who have not had any form of cancer other than minor skin cancers. If you feel that this describes you, we can go on. Should I continue? (Note to Recruiters: We are looking for women who have not had any cancer other than basal cell or squamous cell skin cancer)

If no:

Would you be willing to tell me why you think this does not describe you? (IF WILLING, WRITE DOWN THE ANSWER ON THE CONTACT SHEET.)

Well, since you do not think that you are eligible for the study, we do not need to take any more of your time. Thank you for being willing to hear more about the study. If you want any more information about the study, I would be glad to answer your questions if I can, or you can always check the website for the study, which is listed on the brochure you received in the mail. The website also has information links about cancer care and treatment.

If yes, they have not had any cancer other than the above skin cancers:

I would like to verify that you live in New York City six or more months out of the year. (If they ask why, explain that in order for our results to scientifically be valid, participants must reside in NYC six or more months out of the year.)

If no, let them know they do not qualify for the study and thank them for their time.

If yes, then continue:

I'll just take a minute to give you some background information: Doctors and researchers are concerned, because breast cancer is becoming more common, and not much is known about what causes it or how to prevent it. Scientists at Mount Sinai are running a study to try to learn some of the causes of breast cancer. This study will compare women who have had breast cancer to women who have not, to learn why some get cancer and others do not.

I want to tell you right at the start that there is no cost to you. In fact, you will receive a \$25 gift certificate to either Pathmark or Rite Aide as our way of thanking you for participating in our study. And I want you to know that your privacy is always protected. Only limited study personnel will be aware of your name. From the time of the interview, only an identification number that has been assigned to you will be used, not your name. Do you have any questions for me so far?

I would like to schedule an appointment for you to meet with a female interviewer from Mount Sinai at one of our interview sites and we will, of course, provide a Metrocard to cover travel expenses. At the interview, you will be asked questions about your diet, health history, and other lifestyle habits. Also, a small blood sample and body measurements, such as height and weight, will be taken. This will probably take about two hours. You will NOT be asked to take any drugs or submit to any procedures other than those we have described. We conduct interviews in many locations throughout the city. I'm sure we can find a location near you, or else we can, of course, come to your home, if you would prefer. Do you have any questions?

(IF THEY HAVE QUESTIONS THAT YOU DO NOT KNOW THE ANSWER TO, TELL THEM AN INTERVIEWER WILL CALL BACK TO ANSWER THEIR QUESTIONS).

Do you think you would be able to participate in this study? (YES)_____ (NO)_____

(IF NO, TRY TO FIND OUT WHY AND TRY TO RESPOND TO HER CONCERNS. IF IT WOULD HELP, REFER TO Q&A NUMBER 5 REGARDING CANCER HISTORY. IF THEY STILL SAY NO, ASK):

May I ask you just a few short questions about your socioeconomic background and medical and reproductive history on the phone? The information you would provide will help the researchers to determine whether there is a difference between the women who agree to participate in the study and those who do not agree to participate. Your name will not be attached to your comments and I will be the only person who knows who says what. You can decide not to answer any question you don't like at any time.

Do you agree to participate in this short telephone survey? (YES)_____ (NO)_____

(If YES, See Refuser Questionnaire)

(IF THEY AGREE TO PARTICIPATE, SAY):

That's great. I will be happy to set up an appointment for you. Which borough would you prefer?

☐ Manhattan – we have 3 locations:

- ☐ On the Upper East Side: **Mount Sinai Research Center** at 98th Street and 5th Avenue
- ☐ On the West Side: **St. Luke's Roosevelt Hospital** on 59th Street and 9th Avenue
- ☐ and downtown at **Beth Israel** at Union Square (14th Street)

☐ Queens – **Queens Hospital Center**, 164th Street in Jamaica

☐ Kings County/Brooklyn – **Kings County Hospital** – 451 Clarkson Avenue

☐ The Bronx – **Weiler/Einstein Hospital** – 1695 Eastchester Road

☐ Participant's Home

Recruiter will check which is the selected location.

DAY INTERVIEW SCHEDULED: _____ **DATE:** _____ **TIME:** _____

I will let the Interviewers know you are interested in being in the study, and one of them will call to confirm the interview appointment. Is this the best phone number at which to reach you?

(IF YES, WRITE DOWN THE PHONE NUMBER THAT YOU CALLED.
OR, IF THERE IS A BETTER NUMBER, WRITE IT DOWN HERE).

(____)____-____ Is there a good time of day to call you? **TIME:** _____.

Ok, so one of our Interviewers will be calling you soon to confirm your interview appointment and send you complete directions:

on _____ (**Date**) at _____ (**Time**) and she'll be meeting you at:

Home: _____ **Hospital:** _____ **Other:** _____

If you should want to speak with someone before the Interviewer calls, let me give you our phone number: 866-223-2219 or 212-659-5406. Thank you so much for your time, and for agreeing to be in this important study.

10/14/04

Section: Recruitment Tools/Techniques

Date assigned _____

Date to notify MSSM staff
& return contact sheet _____

Date recruiter returned
contact sheet to MSSM _____

MSSM BREAST CANCER RESEARCH CASE CONTACT SHEET

ID NUMBER: _____ REFERENCE DATE _____ AGE: _____

PARTICIPANT'S NAME: _____

PHONE NUMBER: _____ ETHNICITY: _____

PARTICIPANT'S ADDRESS: _____

REFERRED BY: MD _____ HOSPITAL _____ (NAME)

RECRUITER'S NAME: _____

INTERVIEWER'S NAME: _____

SCHEDULED INTERVIEW DAY: _____ DATE: _____ TIME: _____

ATTEMPTS

Date	Time	Comments	Participation		Meeting Place		
			Yes	No	Home	Hospital	Other

Recruiter, please check the following words that apply to the participant you called. Also write down any additional comments that the participant made or your feelings about your conversation.

- | | | |
|--|------------------------------------|--|
| <input type="checkbox"/> Enthusiastic | <input type="checkbox"/> Nervous | <input type="checkbox"/> Not sure if they want to participate |
| <input type="checkbox"/> Excited | <input type="checkbox"/> Hesitant | <input type="checkbox"/> Would like more information about the study |
| <input type="checkbox"/> Willing to help | <input type="checkbox"/> Angry | <input type="checkbox"/> Questions for staff about the study |
| <input type="checkbox"/> Pleasant | <input type="checkbox"/> Depressed | |

Additional Comments: _____

If Answering Machine: "I'm calling regarding a study at Mount Sinai and I will call back (specific time) or you may reach Senaka Peter at Mount Sinai by calling 1-866-223-2219 or 212 659-5406."

10/14/04

Reference: Recruitment Tools/Techniques

ID NUMBER: _____ REFERENCE DATE: _____

Please attempt to call subjects at least once between 9-11 a.m.; 1-5 p.m.; and 7-8 p.m. before determining whether you can reach them. Please attempt to contact this subject at least 5 times before _____ (return date)

PARTICIPANT RECRUITMENT FORM

[FORM FOR CASES, WOMEN WITH BREAST CANCER]

Hello, may I speak with _____
(WOMAN'S NAME)

(ONCE WOMAN IS ON THE PHONE):

Hello, my name is _____. I'm a breast cancer survivor (since _____ year of diagnosis, optional), involved in outreach for the Mount Sinai School of Medicine. You should have received a letter from Dr. _____ and the researchers here, as well as a postcard from me, telling you about an important study on breast cancer taking place at Mount Sinai Medical Center (and REFERRING HOSPITAL). Your doctor told us that you have indicated an interest in meeting with one of the interviewers for this study. If you have time, I would like to tell you about the study to help you decide whether or not you want to participate.

If **no**:

ASK FOR A BETTER TIME TO CALL BACK. TIME: _____

If **yes**:

I'll just take a minute to give you some background information:

Doctors and researchers are concerned, because breast cancer is becoming more common in women, and not much is known about what causes it or how to prevent it. Doctors at the Cancer Center are running a study to try to learn some of the causes of breast cancer. This study will compare women who have had breast cancer to women who have not, to learn why some get cancer and others do not. Before being diagnosed with this recent breast cancer, did you ever have breast cancer before, or any form of cancer other than basal cell or squamous cell skin cancer? **IF YES, FIND OUT WHAT TYPE OF CANCER, LET THEM KNOW THEY DO NOT QUALIFY FOR THE STUDY AND THANK THEM FOR THEIR TIME.**

IF THEY HAVE NOT HAD OTHER THAN THE ABOVE SKIN CANCERS, CONTINUE:

I would like to verify that you live in New York City six or more months out of the year. (If they ask why, explain that in order for our results to scientifically be valid, participants must reside in NYC six or more months out of the year.) If no, let them know they do not qualify for the study and thank them for their time. If yes, then continue:

I want to tell you right at the start that you do not have to agree to participate. If you do decide to participate, it will not cost you anything. People who agree to participate will be given a \$25 gift certificate from either Pathmark or Rite Aide as our way of thanking you for participating in our study. We will also provide a Metrocard for participants who need to travel in order to participate in this study. The privacy of everyone who participates will always be protected. No one other than the researchers will know who participated or who said what. Any information that is obtained will have a code number on it, not a name. You should also know that this is not a treatment study. If you decide to participate, it will not interfere with any treatment you may be having now or in the future. This study involves being interviewed by a woman who is a trained interviewer. She will be asking questions about diet, health history, and life style habits. She will take some measures of height, weight, and body size and will take a small sample of blood. These procedures will take about two hours. Do you have any questions for me so far?

(IF THEY HAVE QUESTIONS THAT YOU DO NOT KNOW THE ANSWER TO, TELL THEM AN INTERVIEWER WILL CALL BACK TO ANSWER THEIR QUESTIONS).

Do you think you would be interested in participating or at least learning more about the study before you decide? (YES)_____ (NO)_____

(IF NO, TRY TO FIND OUT WHY AND TRY TO CHANGE THEIR MIND. IF IT WOULD HELP, REFER TO Q&A NUMBER 5 REGARDING CANCER HISTORY. IF THEY STILL SAY NO, ASK): May I ask you just a few short questions about your medical history and socioeconomic background on the phone? (See Refuser Questionnaire)

(IF THEY AGREE TO PARTICIPATE, SAY):

That's great. I would like to schedule an appointment for you to meet with a female interviewer from the Cancer Center at one of our interview sites. (Offer Mount Sinai to all women and, as an alternative, a hospital in their borough) The interview can be conducted in **Manhattan** at either Mount Sinai Hospital, 98 St. & Fifth Ave. or St. Luke's Roosevelt Hospital, 59 St. & 9th Ave.; in **Queens** at Queens Hospital Center, 164th St. Jamaica, in **Brooklyn** at Kings County Hospital in Brooklyn (primarily Mondays and Fridays), or in the **Bronx** at either Montefiore Medical Center, East 210th St. or Albert Einstein College of Medicine on Eastchester Road (primarily Wednesdays or Fridays), whichever is more convenient for you. That's all there is to it. So, do you have any questions?

If the hospital sites are not acceptable, offer to have the interview done in their home.

I will be happy to set up an appointment for you. Will you be coming to Mount Sinai or do you prefer _____ hospital? What is a good time and day for you?

INTERVIEW LOCATION: _____
DAY INTERVIEW SCHEDULED: _____ DATE: _____ TIME: _____

I will tell let the Interviewers know you are interested in being in the study, and one of them will call to confirm the interview appointment. Keep in mind that even though you agreed to meet with the interviewer that you can change your mind at any time – even after you start the interview. But I am hoping that you will participate. Is this the best phone number at which to reach you?

(IF YES, WRITE DOWN THE PHONE NUMBER THAT YOU CALLED.
OR, IF THERE IS A BETTER NUMBER, WRITE IT DOWN HERE).

(____)____-____ Is there a good time of day to call you? TIME: _____.

Ok, so one of our Interviewers will be calling you soon to confirm your interview appointment on _____ (Date)at _____ (Time) and she'll be meeting you at:

Home: _____ Hospital: _____ Other: _____
If Hospital/Other, indicate building/room number: _____

If you should want to speak with someone before the Interviewer calls, let me give you the name and phone number of a contact person: (interviewer's) phone number: _____.
Thank you so much for your time, and for agreeing to be in this study.

Date Directions Sent _____

10/14/04

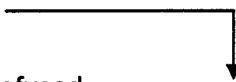
Section: Recruitment Tools/Techniques

REFUSER QUESTIONNAIRE

1. What is your date of birth?

____/____/____
Month Day Year

2. Do you consider yourself to be of Latina or Hispanic origin?

- 1 ☐ Yes
2 ☐ No
9 ☐ DK /Refused
- 

If YES: Do you consider yourself to be any of the following?
(Check all that apply)

- 1 ☐ Mexican/Mexican American/Chicano
2 ☐ Puerto Rican
3 ☐ Cuban
4 ☐ Caribbean or West Indian
5 ☐ Dominican
6 ☐ Other (please specify): _____

3. What is your race?

- 1 ☐ White
2 ☐ Black/African American
3 ☐ Black-Other
4 ☐ Black-West Indian / Caribbean
5 ☐ American Indian or Alaska Native
6 ☐ Asian Indian
7 ☐ Chinese
8 ☐ Filipino
9 ☐ Korean
10 ☐ Vietnamese
11 ☐ Other Asian
12 ☐ Native Hawaiian
13 ☐ Guamanian or Chamorro
14 ☐ Samoan
15 ☐ Other pacific Islander
16 ☐ Some other race

4. What is the highest grade or year of school you have completed?

- 1 ☐ Less than 8th grade
2 ☐ 8th to 11th grade

- 3 ☐ High school graduate or equivalent (GED)
- 4 ☐ Technical or vocational school
- 5 ☐ Some college
- 6 ☐ College graduate
- 7 ☐ Post-graduate degree
- 9 ☐ DK/Refused

5. Do you have a mother, sister or daughter that has had breast cancer?

- 1 ☐ Yes
- 2 ☐ No
- 9 ☐ DK /Refused

6. Have you ever had a mammogram?

- 1 ☐ Yes
- 2 ☐ No
- 9 ☐ DK /Refused

7. During your lifetime, how many mammograms have you ever had?

____ (number) ☐ DK /Refused

8. What type of health insurance do you have?

- 1 ☐ Medicaid
- 2 ☐ Medicare
- 3 ☐ Employer-provided insurance (Oxford, Blue Cross/Blue Shield, HIP)
- 4 ☐ Pay for insurance out of pocket
- 5 ☐ I do not have health insurance
- 6 ☐ Other: _____
- 9 ☐ DK/Refused

9. How old were you when you had your first menstrual period?

____ (years) ☐ DK /Refused

10. How many SONS do you have? _____ (number of sons)

11. How many DAUGHTERS do you have? _____ (number of daughters)

12. Have you gone through menopause, or the change of life?

- 1 ☐ Yes
- 2 ☐ No
- 9 ☐ DK /Refused

13. Have you ever taken birth control pills?

- 1 ☐ Yes

- 2 ☐ No
9 ☐ DK /Refused

14. Have you ever taken hormone replacement therapy?

- 1 ☐ Yes
2 ☐ No
9 ☐ DK /Refused

15. Do you currently smoke cigarettes?

- 1 ☐ Yes
2 ☐ No
9 ☐ DK /Refused

If no, did you ever smoke regularly?

- 1 ☐ Yes
2 ☐ No
9 ☐ DK /Refused

16. In the past year, how many times in a typical WEEK did you participate in moderate physical activity for at least 30 minutes per day?

____ (number of times per WEEK) ☐ DK /Refused

17. One year ago, how much did you weigh?

WEIGHT:

POUNDS.....1
KILOGRAMS.....2

Thank you for your time and helping the Mount Sinai School of Medicine.

10/14/2004
Reference: Recruiting Tools/Techniques

V.

Resources

Buddy System

Expense Report Forms

Staff Listing

Sample Recruiter Post-Card

Sample Brochure

Women's Health Resources

10/14/04

Reference: Resources

BUDDY SYSTEM

The “buddy system” was developed to enhance communication between interviewers and recruiters throughout the recruitment phase. Therefore, each interviewer is matched to a recruiter. If recruitment packets are mailed to recruiters, interviewers will contact recruiters to inform the recruiters of how many potential subjects they are mailing to the recruiter as well as how many are **priority**.

Neon labels will be attached to those cases which must be contacted immediately (within 48 hrs). If a recruiter cannot reach a priority case within this amount of time, they need to contact their interviewer buddy, to let them know. This way, the interviewer can assist the recruiter. It is imperative that we do not lose any potential subjects, due to the late diagnosis date.

Whether or not there are new subjects packets to send, interviewers will contact their recruiter buddies once per week, to see how they are, to ask about recruitment progress, and to see if they have any questions or problems.

Recruiters have **14 days** from the “mail date” to contact their potential subjects. After 14 days, recruiters should return the information in the postage paid envelope.

Section: Resources
10/14/04

RECRUITER/INTERVIEWER BUDDIES

Recruiters/Interviewers

Interviewer: Rose Bialecki	Sherly Jacob	Melissa Solis	Yahaira Kane
Recruiters:			
Iris Mendez (718) 798-5345 (917) 447-3976 (cell)	Carol Copeland (212) 864-0867 (H) (212) 234-1447	Alice Jaworsky (718) 721-1355	Glorie Browne (212) 368-3868 (917) 913-0120 (cell)
	Pat Drew (212) 410-1309	Cathy Williams (718) 981-1673 (H) (347) 728-8289 (cell) (718) 981-8680 (W)	

10/14/04
Reference: Resource

Mount Sinai Recruiter Reimbursement Form

Name (Please Print)

Social Security Number

Your Complete Mailing Address

Your Signature:

Date:

Date	ID #	Participate		Interviewer	Scheduled Interview Date	Interviewed (Staff Only)
		Yes	No			

BELOW IS TO BE COMPLETED BY STAFF

_____ x \$5 = _____
of contacts who **will not** participate per contact

_____ x \$15 = _____
of contacts who **will** participate per contact

50 Scheduled Interviews Completed: x \$50 = _____

Total Reimbursement = _____

11/18/02

STAFF LISTING

	<u>Office Number</u>	<u>Mobile Phone</u>	<u>Beeper</u>
Lina Jandorf, M.A., Principal Investigator, Core A	(212) 659-5506	(917) 650-3751	(917) 424-0702
Christine Ambrosone, Ph.D., Principal Investigator, Project 1	866-223-2219		
Heiddis Valdimarsdottir, Ph.D., Principal Investigator, Project 2	(212) 659-5559		
Dana Bovbjerg, Ph.D., Principal Investigator, Project 3	(212) 659-5562		
Julie Britton, Ph.D. Co-Investigator, Project 1	(212) 241-5488		
Senaka Peter, M.P.H., Project Coordinator	(212) 659-5406		
Rose Bialecki, B.A., Field Work Supervisor	(212) 659-5473	(917) 607-3195	
Sherly Jacob, B.A., B.S., Research Interviewer	(212) 659-5405	(917) 650-4835	
Melissa Solis, B.A., Research Interviewer	(212) 659-5540	(917) 519-8031	
Yahaira Kane, B.A., Research Interviewer	(212) 659-5597	(917) 519-9425	

10/14/04
Reference: Resources



Women's Health Resources

Support & Social Services

American Cancer Society

Service(s): Screenings, Education, and Support Groups

National

Telephone: (800) ACS-2345 (800-227-2345)

Local

Location: Brooklyn: 148 Pierrepont Street, Brooklyn, NY

Telephone: (718) 237-7850

Location: Harlem: 271 West 125th Street b/w 7th & 8th Avenue; Rm. 210, New York, NY

Telephone: (212) 586-8700

Location: Queens: 97044 Queens Boulevard, Suite 110- Rego Park, NY

Telephone: (718) 263-2224

Location: Staten Island: 58 New Dorp Plaza

Telephone: (718) 987-8871

Web address: www.cancer.org

Arthur Ashe Institute for Urban Health/Black Pearls Program

Service(s): Breast-health literature and workshops for African-American women

Location: 450 Clarkson Avenue, Box 1232- Brooklyn, NY

Telephone: (718) 270-3101

Camp Good Days and Special Times, Inc.

Services: Vacation for survivors and their families

Telephone: 1-800-735-2135

CancerCare

Services: Counseling, education, support groups general information and referral and direct financial assistance for all cancers

Hours: Monday-Thursday: 9:00-7:00; Friday: 9:00-5:00

Location: call for details

Telephone: (212) 302-2400 or (800) 813-HOPE (800-813-4673)

Web address: www.cancercare.org

Cancer Hope Network

Services: Provides opportunity to talk with another cancer survivor based on same or similar type of cancer, stage, treatment, age, gender, ethnicity, etc.

Telephone: (877) 467-3638

Web address: Info@cancerhopenetwork.org

Cancer Information Service (CIS)- National Cancer Institute:

Service(s): Telephone-based cancer information and written literature on various cancer topics and issues
Telephone: (800) 4 Cancer (800-422-6237)
Web address: www.cancer.gov

Gilda's Club- New York

Service(s): Education, support groups, stress management and social events
Hours: Monday-Friday: 9:00-5:00
Location: 195 West Houston Street- New York, NY
Telephone: (212) 647-9700
Web address: www.gildasclubnyc.org

Partnership of Cancer Centers of Beth Israel & St. Luke's/Roosevelt & SHARE

Service(s): Yoga, Meditation, Ongoing Breast Support
Location: call for details and to register
Telephone: Cancer Centers of St. Luke's/Roosevelt Hospitals: (212) 523-7082
Beth Israel Cancer Center: (212) 844-6022

Project S.H.E. (Support · Heal · Educate)

Service(s): Education and information
Location: 467 West 143rd Street, Suite 3; New York, NY
Email: projectshe@yahoo.com
Web address: www.projectshe.org

Community Outreach Program, Albert Einstein College of Medicine

Service(s): Individual and group counseling; research, education
Location: 1300 Morris Park Avenue, Bronx, N.Y. 11461
Telephone: (718) 430-2696
Web address: www.aecom.yu.edu/cancer/outreach

SHARE (Self-help for women with Breast or Ovarian Cancer)

Service(s): Support groups for survivors, relatives and exercise and wellness programs
Location: 1501 Broadway, Suite 1720; New York, NY 10036
Telephone: (212) 719-0364; (800) 891-2392

SHAREing & CAREing

Service(s): Support groups, volunteer services, information, financial counseling, childcare and advocacy
Location: 30-60 Crescent St., Suite B, Astoria, NY 11102
Telephone: (718) 777-5766

Sister's Network

A national African-American Breast Cancer Survivors' Organization

(731) 781-0255 phone national headquarters

Web address: www.sistersnetworkinc.org

Mahogany Sister's Network- Queens New York Chapter

Location: P.O. Box 204- Brooklyn, NY 11207

Telephone: (718) 723-5879

Sister's Network-Long Island New York Chapter

Location: 734 Franklin Avenue- Garden City, NY

Telephone: (516) 538-8086

The Jean Sindab African American Breast Cancer Project- New York –Presbyterian Hospital, Columbia Presbyterian Center

Service(s): Research, Education and information

Telephone: (212) 305-6816

Web address: www.sindab.org

The National Black Women's Health Project

Local Office: 485 Lenox Avenue- New York, NY

Telephone: (212) 368-1602; national office: (202) 543-9311

Web address: www.nbwhp.org

The Susan G. Komen Breast Cancer Foundation

Service(s): funding for breast cancer research, information and education

New York Affiliate:

341 West 38th Street, 10th floor; New York, NY 10018

(212) 560-9590 phone or 800-I'M AWARE (800-462-9273)

Web address: www.komen.org

Y-Me National Breast Cancer Organization

Service(s): Education, support services and newsletter

Location: 212 West Van Buren, 5th fl; Chicago, IL 60607-3908

Telephone: (800) 241-2141

(800) 986-9505 en espagnol

Web address: www.y-me.org

Young Survival Coalition (Young Women against Breast Cancer)

Seeks to increase awareness of breast cancer and to advocate for increased funding and technological advancement with a particular focus on young women

Service(s): Support Groups, Education, and Advocacy

Telephone: (212) 916-7667

Web address: www.youngsurvival.org

Encore^{PLUS®} YWCA of the United States of America

Service(s): Exercise and recreation

Target: women recovering from breast surgery

Location: call for details

Telephone: (212) 735-9797

Post-Mastectomy Retail Stores

Underneath It All

Service(s): A post breast surgery comprehensive shopping service

Hours: Monday-Thursday: 10:00-6:00

Location: 444 East 75th Street- New York, NY

Telephone: (212) 717-1976

Yvette Lingerie and Post-Mastectomy Boutique

Service(s): Counseling and products for women with breast cancer

Location: 40-13 Bell Boulevard- Bayside, NY

Telephone: (718) 229-5724

Email: YvetteLingerie@aol.com
Web address: www.YvetteLingerie.com

Paulette Gay

Service(s): Scarves, head wraps, workshops
Location: 408 Lenox Avenue, New York, N.Y. 10039
Telephone: 212 862-7369

▪ **My Secret**

Services: Products for women with breast cancer
Location: 86th Street and Columbus Ave., New York, N.Y.

Financial/Health Insurance

Health Insurance Association of America

Service(s): hotline for general consumer information
Fee: Free
Telephone: (202) 824-1600

Medical Assistance Research Program of New York City

Service(s): eligibility information about Medicaid
Telephone: (212) 273-0047/49

Resource Entitlement and Advocacy Program (REAP)

Service(s): advocacy, assistance with entitlements
Location: Mount Sinai Medical Center
2403-05 Madison Avenue at 97th Street; New York, NY
Telephone: (212) 423-2800

**The Health Insurance Information, Counseling & Assistance Program (HICAP)
Insurance Help**

Service(s): advocacy, assistance with Insurance counseling, assistance and information
Telephone: (212) 869-3850; (800) 333-4114

Breast and Cervical Cancer Screening

American Italian Cancer Foundation

Service(s): Breast health and Screenings, Mobile van service
Fee: free
Hours: Monday-Friday: 9:00-5:00
Location: call for details
Telephone: (800) 564-6868 or (212) 628-9090
Web address: www.aicfonline.org

Bronx Breast-Health Partnership- Bronx Lebanon Hospital Center:

Service(s): Breast and Cervical Health and Screenings
Fee: low or no cost
Location: 1650 Grand Concourse-Bronx, NY
Telephone: (718) 920-1724

Brooklyn Breast- Health Partnership:

Service(s): Breast Screenings and Cervical Examinations
Fee: low or no cost
Location: 30 Third Avenue, Brooklyn
Telephone: (718) 875-1019

Boriken Neighborhood Health Center:

Service(s): Clinical Breast and Cervical Examinations, General Health and Social Services
Fee: sliding scale
Hours: Monday & Wednesday: 8:30-7:00; Tuesday, Thursday & Friday: 8:30-5:00
Location: 2253 Third Avenue, Third floor b/w 122nd and 123rd Streets, New York, NY
Telephone: (212) 289-6500

Breast Examination Center of Harlem (BECH)- Memorial Sloan-Kettering Cancer Center

Service(s): Breast & Cervical Health, Screenings, Education and Support Services
Fee: free
Hours: Monday-Friday: 8:30-4:00
Location: State Office Building-163 West 125th Street, corner of Adam Clayton Powell, Jr. (7th Avenue), 4th floor
Telephone: (212) 531-8000
Web address: www.mskcc.org

Callen-Lorde Community Health Center

Service(s): Breast and Cervical health and senior wellness programs
Location: 356 West 18th Street b/w 8th and 9th Avenues- New York
Hours: M: 12:30-8p; W: 8:30a-8p; T, Th & F: 9a-4:30p
Telephone: (212) 271-7200

Cancer Institute of Brooklyn at Maimonides Medical Center

Service(s): Breast Health and screenings, social and support services, community outreach
Language: English, Spanish, Russian and Chinese
Telephone: (718) 283-6955

Columbia University Breast-Cancer Screening Partnership:

Service(s): Breast Health and Screenings
Fee: low or no cost
Location: Columbia Presbyterian Center- Atchley Pavilion, 10th floor; 161 Fort Washington Avenue, New York, NY
Telephone: (212) 305-0163

Continuum Health Partners

Beth Israel · St. Luke's Roosevelt · Long Island College · NY Eye & Ear Infirmary
Service(s): Mammography screening
Fee: Free
Target: women 50 and over with and without insurance
Location: call for details and to make appointment
Telephone: (212) 844-8772

Cumberland Diagnostic & Treatment Center

Service(s): Breast and Cervical Health, Cancer Screenings, Counseling and Education

Location: 100 North Portland Avenue- Brooklyn, NY
Telephone: (718) 260-7500

Kings County Hospital Center

Services (s): Breast and Cervical Health and General Health
Telephone: (718) 245-3267

Lenox Hill Hospital Health Education Center

Service(s): Breast Health, Education and Information
Fee: low or no cost
Location: 1080 Lexington Avenue- New York, NY
Telephone: (212) 434-2980
Web address: www.lenoxhillhospital.org

Manhattan Breast Health Partnership:

Service(s): Breast Health and Screenings
Fee: low or no cost
Location: call for details
Telephone: (212) 586-8700

Metropolitan Hospital Center- Women's Health Clinic

Service(s): Breast & Cervical Health, General Health and Support Groups
Fee: call for details
Hours: Monday-Friday: 9:00-4:00
Location: 1901 First Avenue b/w First and Second Avenues New York, NY

Mount Sinai /NYU Health

Service(s): Breast and Cervical Examinations, General Health, Genetic Testing and Education
Fees: call for details
Location: 1190 Fifth Avenue, New York, NY
Telephone: (800) MD-SINAI (800-637-4624)

Mount Sinai Breast Health Resource Program

Service(s): Support, counseling, stress management, health education, information and screening referrals
Fees: call for details
Location: 16 East 98th Street- New York, NY
Telephone: (212) 987-3063

National Black Leadership Initiative on Cancer- Cancer Control Center of Harlem Hospital

Service(s): Breast and Cervical Health and Screenings
Fee: Free
Hours: Thursdays: 12:00-3:00; Saturdays: 9:00-12 noon
Location: Harlem Hospital Center- Ronald H. Brown Pavilion
530 Lenox Avenue at West 137th Street b/w Lenox and Fifth Avenues New York, NY
Telephone: (212) 939-8034 or (212) 939-8051

Queens Healthy Women Partnership:

Service(s): Breast Health and Screenings
Fee: low or no cost

Location: ACS Queens- 97044 Queens Boulevard, Suite 110- Rego Park, NY
Telephone: (718) 263-2224

Settlement Health

Service(s): Clinical Breast and Cervical Examinations, General Health and Social Services
Fee: sliding scale
Hours: Monday & Friday: 9-4:45; Wednesday: 10-4:45; Tuesday & Thursday: 9-6:45;
Saturday 9-12:45
Location: 212 East 106th Street b/w Third and Second Avenues, New York, NY
Telephone: (212) 360-2600

Sister-to-Sister Full Circle of Care Breast Cancer Program

Service(s): Breast Health and Screenings, Education and Social Services
Fee: low or no cost
Hours: call for details
Location: ACS Brooklyn & ACS Harlem
Telephone: (212) 663-8800 or (718) 237-7850

St. Luke's Roosevelt Hospital Breast Clinic- Breast Health Partnership

Service(s): Breast Health and screenings
Fee: Low or no cost
Location: 1111 Amsterdam Avenue- New York, NY
Telephone: (212) 573-4000

Staten Island Breast Health Partnership

Service(s): Breast & Cervical Health and screenings
Fee: Low or no cost
Location: 58 New Dorp Plaza- Staten Island, NY
Telephone: (718) 987-8871

The William F. Ryan Community Center

Service(s): Breast and Cervical Health and Screening
Fee: sliding scale
Hours: Monday & Thursday: 9:00-1:30; Tuesday, Wednesday & Friday: 9:00-5:00
Location: 110 West 97th Street, New York, NY
Telephone: (212) 749-4820

World Wide Web Based Information & Resources

AVON- Avon Breast Cancer Crusade

Web address: www.avoncompany.com/women/avoncrusade

CancerCare

Web address: www.cancercare.org

Cancer Information Service (CIS)- National Cancer Institute

Web address: www.cancer.gov

Gynecologic Cancer Foundation

Web address: www.wcn.org

Look Good...Feel Better

Web address: www.lookgoodfeelbetter.org

National Alliance of Breast Cancer Organizations

Web address: www.nabco.org

Sister's Network

Web address: www.sistersnetworkinc.org

The Breast Cancer Site

Web address: www.thebreastcancersite.com

The Susan G. Komen Breast Cancer Foundation

Web address: www.komen.org or www.breastinfo.org

Y-Me National Breast Cancer Organization

Web address: www.y-me.org

Young Survival Coalition (Young Women against Breast Cancer)

Web address: www.youngsurvival.org

CORE B

“Molecular, Diagnostics and Research Core”

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Core B: "Molecular, Diagnostics and Research Core"

Principal Investigator: Dr. Margaret McGovern

INTRODUCTION:

The Molecular Diagnostic and Research Core of the Center for Interdisciplinary Biobehavioral Research will provide expert molecular studies to identify: 1) molecular changes in two genes, BRCA 1 and 2, which are associated with breast cancer; and 2) molecular changes in DNA that are associated with variability in level of production of certain proteins that are normally found in the body that also may effect cancer risk. These analyses will permit the investigators of the Center to assess the impact of these genetic factors on cancer risks, and on the psychobiology of the interaction of generic factors with family history, stress and ethnicity. The Molecular Diagnostic and Research Core investigators will work with the individual project directors to identify relevant genetic risk factors, establish laboratory analyses to detect their presence in study subjects, and carry out all molecular analyses as per the individual study protocols. The Core directors will work closely with the center investigators in developing cost efficient protocols for the molecular testing.

BODY:

Task 1. To establish the methodology for complete sequencing of BRCA 1 and 2

The methodology for the full sequencing of BRCA 1 and 2 has been established in the core laboratory. In addition QA and QC measures have been established and both normal control and know mutation carriers have been sequenced.

Task 2. To establish the methodology for the determination of the genotype of r estrogen receptor genes and polymorphisms.

Allele specific oligonucleotide hybridization technology has been established in the core laboratory for genotyping for polymorphisms. This capability is routinely available and can be scaled up to handle large volumes of samples if required.

Task 3. Sequencing of BRCA 1 and 2 genes using DNA from subjects recruited from Project 2

No specimens have been received by the core laboratory to date.

Task 4. Determination of genotypes for estrogen receptor polymorphisms.

No specimens have been received by the core laboratory to date.

Task 5. Determination of the genotype for polymorphisms in TNFa

No specimens have been received by the Core Laboratory to data.

Task 6. Integration of Core laboratory into activities of training core.

The Core Laboratory professional staff provides educational sessions to trainees and investigators. The Core Laboratory Principal Investigator also is offering a course in the Fall 2004, which is open to trainees and investigators. This course, entitled "Molecular for the Clinical Investigator" includes a series of lectures on the application of molecular techniques in clinical investigation.

KEY RESEARCH ACCOMPLISHMENTS:

None.

REPORTABLE OUTCOMES:

The Core Laboratory has established a system for the storage and retrieval of study specimens that will safeguard confidentiality and ensure accurate retrieval. The laboratory has worked with the project PIs in the establishment of a system for the storage of specimens in a straw system.

CONCLUSIONS:

At this point in the research, no results are yet available.

REFERENCES:

None

APPENDICES:

None

CORE C

"Biostatistics and Data Management Core"

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Core C: "Biostatistics and Data Management Core"

Principal Investigator: Dr. James H. Godbold

INTRODUCTION:

The three projects in this Center project will each collect data to address their study hypotheses. It is extremely important that the data that are collected be managed in a careful way and that the analyses that are performed on the data use statistics that lead to valid conclusions.

The objective of the Biostatistics and Data Management Core is to provide databases for entry, storage, and retrieval of data collected in the three projects of this Center. The quality of the data will be monitored at each step in the process. The Core will also provide statistical analyses of the data using appropriate models to address the specific aims/objectives of each project.

Without good management of data, cleaning of data to provide a valid dataset, and appropriate statistical analyses of the collected data, the work in three projects would be of little value. The members of this Core will work closely with the investigators of the three projects and members of the other Cores to coordinate the data activities so that this work is done in a timely manner.

BODY/ KEY RESEARCH ACOMPLISHMENTS:

During the past year the Biostatistics and Data Management Core has modified the tracking database to facilitate the recruitment of subjects into the three Projects. Also, the databases for each of the projects' data have been finalized for receipt of questionnaires.

We are prepared to begin data entry for Project 1, and the progress of data entry will keep pace with recruitment. The data entry process will be one of double entry with resolution of difference on a point by point basis.

Flowcharts are generated bi-weekly to aid investigators in monitoring the progress of subject recruitment. The flowcharts are for the Center as a whole, as well as for each Project.

Programs have been written in SAS for data cleaning of the data collected in the questionnaires. These programs have been implemented, and queries have been generated for data items failing either range or logic checks. The status of these queries, after they have been sent to the project coordinators for resolution, is also being monitored.

REPORTABLE OUTCOMES:

None

CONCLUSIONS:

None

REFERENCES:

None

APPENDICES:

None

CORE D

“Training Core”

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Core D: "Training Core"

Principal Investigator: Dr. Dana H. Bovbjerg

INTRODUCTION:

Breast cancer continues to be a preeminent cause of morbidity and mortality among American women, despite the recent encouraging news that cancer incidence and mortality rates have inched downward in the past decade. The risk of early mortality is a particularly a concern for African American women. African American women are more frequently diagnosed with advanced, aggressive tumors, and those under age 50 have nearly twice the breast cancer risk of white women. The research literature suggests that it is the interaction of behavioral and genetic factors, which may account for clinical findings among African American women. However, few researchers today are equipped with the skills necessary to investigate the interactions among behavioral factors, genetics, and culture. The goal of the Training Core in Biobehavioral Breast Cancer Research is to foster the development of interdisciplinary researchers focused on epidemiological and biobehavioral aspects of breast cancer that are particularly relevant to African Americans through a broadly based, multidisciplinary postdoctoral training program involving a required curriculum of formal lectures, participation in specialized seminar series, "hands-on" research experience with the guidance of a nationally-recognized research mentor, and formal, as well as hands-on, training in the preparation of research papers and grants. This training will act as a bridge between behavioral and epidemiological approaches to breast cancer research.

BODY:

Since we have had to wait for HSRRB review of our repeatedly amended (at the request of Dr. Pranulis, Human Subjects Protection Scientist, AMDEX) applications for approval through the USAMRAA office for Project 1, 2, or 3, which were intended to provide the research experience for the Trainees supported by this Core (See reports for each Project above), we have intentionally delayed our timeline for completion of the training tasks listed in the Statement of Work of the funded Core (D). In the past year we have, continued to address Task 1: a) recruit applications; b) evaluate potential trainees (done for all received); c) develop and schedule Foundations Curriculum (done for Epidemiology and Behavioral modules); d) coordinate training with ongoing Cancer Center Training Programs (done); e) schedule seminar series (done); f) run Foundations and Seminar Series (done); g) establish hands-on research experience for each Trainee (not done, since HSRRB approval not received); h) schedule and run Luncheon Lecture Series (replaced by weekly Journal Club – done); subsections i) through l) have not been completed due to the delays imposed by the HSRRB review (Dr. Pranulis). However, with two postdoctoral Trainees recruited, we continued our attempts to obtain HSRRB approval required to conduct our research, which would allow us to complete Task 1. We have now obtained approval for Project 1, and need only complete Mt Sinai IRB renewal paperwork for Project 3, however Project 2 is still awaiting action by HSRRB. While awaiting review of our amended applications, we

engaged the Trainees in related research approved by the Mt Sinai Institutional Review Board for protection of human subjects, and funded by other sources. This report constitutes partial completion of Task 4 for this Core. We plan to initiate Task 3 during the next 6 months. If HSRRB approval is approved soon, we hope to complete Tasks 3 and 4 by month 72.

KEY RESEARCH ACOMPLISHMENTS:

At this point in the research, with the delay in approval by the HSRRB of the USAMRAA, no results are yet available.

REPORTABLE OUTCOMES:

None at this time.

CONCLUSIONS:

At this point in the research, no results are yet available. We recruit Trainees and have conducted a broad-based postdoctoral training program to prepare those Trainees for interdisciplinary research in biobehavioral approaches to breast cancer. At the end of the program the Trainees should be ready to pursue independent research careers investigating biobehavioral processes involved in breast cancer and their interactions with minority culture. As a long term benefit of the Core, we anticipate the Trainees' efforts will cumulatively result in a series of research articles addressing some of the more critical minority issues in biobehavioral aspects of breast cancer with potential clinical implications for cancer prevention, screening, diagnosis, treatment, and survival in this underserved population.

REFERENCES:

N/A

APPENDICES:

N/A